Exhibit A

John B. Sganga (State Bar No. 116,211)
Frederick S. Berretta (State Bar No. 144,757)
Joshua J. Stowell (State Bar No. 246,916)
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(650) 838-3600
(650) 838-3699 (FAX)

Attorneys for Plaintiffs and Counter-Defendants
THE LARYNGEAL MASK COMPANY LTD.
and LMA NORTH AMERICA, INC.

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Plaintiffs, v. AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN. BHD., Defendants.	Civil Action No. 07 CV 1988 DMS (NLS) **PLAINTIFFS' FED. R. CIV. P. RULE 26(a) INITIAL DISCLOSURE STATEMENT** Honorable Dana M. Sabraw
AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN. BHD., Counterclaimants, v. THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Counter-Defendants.	

Pursuant to Fed. R. Civ. P. Rule 26(a)(1)(A), Plaintiffs The Laryngeal Mask Company Ltd. and LMA North America, Inc. (collectively "LMA") after making such good faith inquiry and investigation as is reasonable under the circumstances, provide this Initial Disclosure Statement to Defendants Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd. (collectively "Ambu"). LMA reserves the right to supplement, amend or correct this Initial Disclosure Statement in whole or in part.

I. INDIVIDUALS

LMA hereby identifies individuals that are likely to have discoverable information that LMA may use to support its claims or defenses in accordance with Fed. R. Civ. P. 26(a)(1)(A)(i). LMA has provided address and public telephone information where known. In making these disclosures, LMA does not waive its right to object, pursuant to applicable Local and Federal Rules, to the deposition testimony of any of the individuals listed below.

Pursuant to Rule 2-100, California Rules of Professional Conduct, counsel of record for Ambu are hereby notified that the individuals identified below, including but not limited to LMA's current employees, are represented by counsel of record in this matter for LMA or by another lawyer. These individuals may only be contacted through LMA's counsel.

The inventions claimed in the patents-in-suit; the design and development of LMA's laryngeal mask airway devices

1. Dr. Archibald I. J. Brain
Mahe
Seychelles

LMA's laryngeal mask airway devices and sales and marketing thereof in the United States

1. Steven R. Block
President and Chief Executive Officer
LMA North America, Inc.
4660 La Jolla Village Drive, Suite 900
San Diego, CA 92122
(858) 587-4025

///

2. Thomas B. Bendinelli
Director of Sales - West
LMA North America, Inc.
4660 La Jolla Village Drive, Suite 900
San Diego, CA 92122
(858) 587-4025

3. Michael Masilonis
Director of Sales - East
LMA North America, Inc.
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San Diego, CA 92122
(858) 587-4025

4. Derek Evans
Executive Director of Marketing
LMA North America, Inc.
4660 La Jolla Village Drive, Suite 900
San Diego, CA 92122
(858) 587-4025

5. Gary Gill
National Sales Training Manager
LMA North America, Inc.
4660 La Jolla Village Drive, Suite 900
San Diego, CA 92122
(858) 587-4025

Financial statements and related information regarding sales, revenues, and costs associated with LMA's products sold in the United States

1. Michael Briant
Chief Financial Officer
LMC Ltd.
Osprey House, Old Street
St. Helier, Jersey, JE2 3RG, Channel Islands
(44) 1534 712073

2. Michael Warford
Vice President and Corporate Controller
LMA North America, Inc.
4660 La Jolla Village Drive, Suite 900
San Diego, CA 92122
(858) 587-4025

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3. Richard Harnett
Contracts Manager
LMA North America, Inc.
4660 La Jolla Village Drive, Suite 900
San Diego, CA 92122
(858) 587-4025

In addition to the above-identified individuals, other persons whose names appear in the documents described in Section II below may be likely to have discoverable information that LMA may use to support its claims or defenses. LMA expressly reserves the right to identify and call as witnesses additional persons if, during the course of discovery and investigation relating to this case, LMA learns that such additional persons have knowledge or information that LMA may use to support its claims or defenses including, but not limited to, witnesses employed or associated with Ambu or third parties.

II. RELEVANT DOCUMENTS AND TANGIBLE THINGS

LMA describes below categories of documents, electronically stored information, and tangible things in accordance with Fed. R. Civ. P. 26(a)(1)(A)(ii). LMA is in the process of searching for additional documents and information that it may use to support its claims or defenses and expressly reserves the right to supplement this Initial Disclosure with such additional documents and information.

- United States Patent No. 7,156,100 ("the '100 patent" or "the patent-in-suit") and its prosecution file history, including the British priority application;
- Documents and prototypes reflecting the making of the inventions claimed in the '100 patent;
- Agreement assigning rights under the '100 patent from Dr. Brain to The Laryngeal Mask Company Ltd. and patent license agreement under the '100 patent between The Laryngeal Mask Company Ltd. and LMA North America, Inc.;
- Samples of Ambu's "Laryngeal Mask", AuraOnce, Aura40, AuraFlex, AuraStraight, and Aura Standard devices;
- Ambu marketing documents describing Ambu's "Laryngeal Mask", AuraOnce, Aura40, AuraFlex, AuraStraight, and Aura Standard devices;
- U.S. Patent Application Publication No. 2006/0201516;

- Documents submitted by Ambu in prior judicial proceedings and to the U.S. Patent and Trademark Office;

- Articles reporting clinical studies and scientific posters involving LMA's laryngeal mask airway devices and/or Ambu's "Laryngeal Mask", AuraOnce, Aura40, AuraFlex, AuraStraight, and Aura Standard laryngeal mask airway devices;

- Documents relating to the laryngeal mask airway device market, including those related to sales, market share, competition, and associated financial information.

In addition to the above-described documents, LMA may also rely on other publicly available documents and on documents produced by Ambu, LMA or third parties in this or other litigations.

III. COMPUTATION OF DAMAGES

LMA's damages claim for patent infringement is based on 35 U.S.C. § 284, which provides in relevant part:

> "Upon finding for the claimant the court shall award the claimant damages adequate to compensate for the infringement but in no event less than a reasonable royalty for the use made of the invention by the infringer, together with interest and costs as fixed by the court."
>
> "When the damages are not found by a jury, the court shall assess them. In either event the court may increase the damages up to three times the amount found or assessed."

In accordance with Fed. R. Civ. P. 26(a)(1)(A)(iii), LMA claims at least the following categories of damages to compensate for Ambu's infringement of the patent-in-suit. LMA requires discovery to establish the extent of its damages, and therefore has not yet made a computation of any category of its damages.

A. Lost Profits

Ambu has infringed the patent-in-suit through its sale and offering for sale in the United States of its laryngeal mask airway device products. Based on information currently available, but for Ambu's infringing activity, LMA would have made Ambu's sales of laryngeal mask airway device products made to Ambu's customers. LMA requires discovery of at least Ambu to establish the identity of these lost customers and the extent of the resulting lost profits.

LMA seeks to recover its lost profits, including at least those attributable to lost sales of laryngeal mask airway devices due to Ambu's infringing sales and those attributable to the erosion of the price of LMA's laryngeal mask airway devices caused by Ambu's infringing sales.

B. Reasonable Royalty

At a minimum, LMA is entitled to damages "not less that a reasonable royalty" for Ambu's infringing use of the patent-in-suit.

C. Prejudgment Interest, Treble Damages and Attorney's Fees

LMA also claims prejudgment interest from the date of infringement to the date of judgment. LMA will also request that the Court increase the damages by three times, and claims attorney's fees pursuant to 35 U.S.C. § 285.

IV. INSURANCE AGREEMENTS

LMA is not aware of "any insurance agreement under which an insurance business may be liable to satisfy all or part of a possible judgment in the action or to indemnify or reimburse for payments made to satisfy the judgment." Fed. R. Civ. P. 26(a)(1)(A)(iv).

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 28, 2008

By: _____
John B. Sganga
Frederick S. Berretta
Joshua J. Stowell

Attorneys for Plaintiffs
THE LARYNGEAL MASK COMPANY LTD.
and LMA NORTH AMERICA, INC.

CERTIFICATE OF SERVICE

I am a citizen of the United States of America and I am employed in San Diego, California. I am over the age of 18 and not a party to the within action. My business address is 550 West C Street, San Diego, California 92101. I served the within **PLAINTIFFS' FED. R. CIV. P. RULE 26(a) INITIAL DISCLOSURE STATEMENT** on the parties or their counsel shown below, via Email and U.S. Mail, addressing it as follows:

Darryl M. Woo
FENWICK & WEST LLP
555 California Street, 12th Floor
San Francisco CA 94104
dwoo@fenwick.com
T: 415-875-2300
F: 415-281-1350

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Dated: May 28, 2008

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Exhibit B

DARRYL M. WOO (CSB NO. 100513)
CHARLENE M. MORROW (CSB NO. 136411)
RYAN J. MARTON (CSB NO. 223979)
C. J. ALICE CHUANG (CSB NO. 228556)
DENNIS FAIGAL (CSB NO. 252829)
FENWICK & WEST LLP
555 California Street
12th Floor
San Francisco, CA 94104
Telephone: (415) 875-2300
Facsimile: (415) 281-1350

Attorneys for Defendants
AMBU A/S, AMBU INC., AMBU LTD., and
AMBU SDN. BHD.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Plaintiff, v. AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN. BHD., Defendant.	Case No. 3:07-cv-01988-DMS-NLS Jury Trial Demanded **DEFENDANTS AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN. BHD.'s RULE 26(a)(1) INITIAL DISCLOSURES** Judge Dana M. Sabraw Magistrate Judge Nita L. Stormes

Defendants Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd. (collectively "Ambu") by and through their counsel, make the following initial disclosures in the above-captioned matter pursuant to Rule 26(a)(1) of the Federal Rules of Civil Procedure. These disclosures are made based on information reasonably available to Ambu, or in its possession as of this date, following a good faith inquiry in accordance with Rule 26. Ambu's investigation of possible witnesses and documents is ongoing, however, and it reserves the right to supplement, amend, and/or correct the information disclosed herein at appropriate intervals during the litigation, and to rely on such information as evidence in this action in accordance with Rule 26(e).

These disclosures are made without waiver of, or prejudice to, any objection Ambu may have to the use at trial of any of the information disclosed in this document or any document or thing produced pursuant to Rule 26. The inclusion of any individual's identity or the production of any document does not constitute an agreement or concession that the individual will be produced or that the documents are discoverable.

Ambu discloses as follows concerning the subjects in Rule 26(a)(1).

I. Rule 26(a)(1)(A)(i): Individuals Likely to Have Discoverable Information

Ambu[1] identifies the following individuals pursuant to Rule 26(a)(1)(A). All witnesses should be contacted through Ambu's attorneys of record, Fenwick & West LLP, 555 California Street, 12th Fl., San Francisco, CA 94104, Tel: (415) 875-2300.

Name	Position and Contact Information	Subjects of Information
Jens Frimann	Vice President of Research and Development, Ambu A/S	Product development of Ambu's laryngeal mask products.
Henrik Wendler	Executive Vice President, Ambu A/S	Marketing efforts for Ambu's laryngeal mask products.
Henrik Ankjaer	General Manager, Ambu Ltd.	Manufacturing of Ambu's laryngeal mask products.
Frank Homa	General Manager, Ambu Inc.	Sales and marketing efforts for Ambu's laryngeal mask products.

Other individuals likely to have discoverable information on the subject of prior art include: individuals listed in patents, publications, and other references in the file histories of the patent-in-suit and related applications. Ambu incorporates by reference into its disclosures these individuals and their contact information identified in such references. Ambu also incorporates by reference into its disclosures contact information for persons identified on prior art patents,

[1] Ambu Sdn. Bhd. is identifying witnesses out of an abundance of caution because it is named as a defendant in this matter. However, it has never had any involvement in the design, manufacture, sales or other conduct related to accused laryngeal masks.

publications, and/or products it may produce during this litigation.

II. Rule 26(a)(1)(A)(ii): Documents in Ambu's Possession, Custody, or Control

Ambu A/S, Ambu Inc., and Ambu Ltd., disclose the following categories and locations of documents, data compilations and tangible things that are in its possession, custody, or control and that Ambu may use to support its counterclaims and defenses. Ambu Sdn. Bhd. does not have any documents relevant to this matter as it has never had any involvement in the design, manufacture, sales or other conduct related to accused laryngeal masks.

Category of Documents	Location
Product development and technical documents related to Ambu's laryngeal mask products.	Ambu[2]
Patents, publications and products which may constitute prior art	Ambu
Sales and/or financial documents relating to Ambu's laryngeal mask products.	Ambu

III. Rule 26(a)(1)(A)(iii): Computation of Damages

Ambu does not at this time have a claim for damages, but may seek all of its attorneys' fees and costs associated with defending against Plaintiff's lawsuit in an amount which, at this time, is not readily amenable to computation. At a minimum, Ambu intends to seek its fees and costs for defending Ambu Sdn. Bhd. because plaintiffs lack any Rule 11 basis for asserting Ambu Sdn. Bhd.'s participation in the design, manufacture, sales or other conduct related to the accused laryngeal mask products. Ambu reserves the right to assert a damage claim, if appropriate, against Plaintiff at a later stage in this litigation.

IV. Rule 26(a)(1)(A)(iv): Insurance Agreements

Ambu does not currently intend to rely upon any insurance agreements to satisfy part or all of any judgment, which may be entered in this action or to indemnify or reimburse for

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[2] A location of "Ambu" indicates documents, data compilations, and tangible things whose location for the purposes of this litigation is that of the offices of Ambu's counsel, Fenwick & West LLP, located at 555 California Street, 12th Fl., San Francisco, CA 94104, or its offices at 801 California Street, Mountain View, California 94041.

payments made to satisfy any judgment.

Dated: May 28, 2008

FENWICK & WEST LLP

By: Dennis Faigal
Dennis M. Faigal

Attorneys for Defendants
AMBU A/S, AMBU INC., AMBU LTD., and
AMBU SDN. BHD.

CERTIFICATE OF SERVICE

The undersigned declares as follows:

I am a citizen of the United States and employed in Santa Clara County, State of California. I am over the age of eighteen years and not a party to the within-entitled action. My business address is Fenwick & West LLP, 801 California Street, Mountain View, CA 94041. On the date set forth below, I served a copy of the following document(s):

DEFENDANTS AMBU A/S, AMBU INC., AMBU LTD., AND AMBU SDN. BHD.'S RULE 26(A)(1) INITIAL DISCLOSURES

on the interested parties in the subject action by placing a true copy thereof as indicated below, addressed as follows:

Frederick S. Berretta, Esq.
KNOBBE MARTENS OLSON AND BEAR
550 West C Street, Suite 1200
San Diego, CA 92101

Vicki S. Veenker
SHEARMAN & STERLING LLP
1080 Marsh Road
Menlo Park, CA 94025

☒ **BY US MAIL:** by placing the document(s) listed above in a sealed envelope for collection and mailing following our ordinary business practices. I am readily familiar with our ordinary business practices for collecting and processing mail for the United States Postal Service, and mail that I place for collection and processing is regularly deposited with the United States Postal Service that same day with postage prepaid.

I declare under penalty of perjury under the laws of the State of California and the United States that the above is true and correct.

Date: May 28, 2008

Kathryn Maramba

26616/00401/LIT/1285729.2

Exhibit C

John B. Sganga (State Bar No. 116,211)
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Attorneys for Plaintiffs
THE LARYNGEAL MASK COMPANY LTD.
and LMA NORTH AMERICA, INC.

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Plaintiffs, v. AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN. BHD., Defendants.	Civil Action No. 07 CV 1988 DMS (NLS) **PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1 - 83)** Honorable Dana M. Sabraw
AMBU A/S, AMBU INC., AMBU LTD., and AMBU SDN.BHD. Counterclaimants, v. THE LARYNGEAL MASK COMPANY LTD. and LMA NORTH AMERICA, INC., Counter-Defendants	

Plaintiffs The Laryngeal Mask Company, Ltd. and LMA North America, Inc. (collectively "LMA"), by its attorneys and pursuant to Rule 34 of the Federal Rules of Civil Procedure, hereby requests that Defendants AMBU A/S, AMBU INC., and AMBU LTD. (collectively "AMBU") produce the documents and things described herein for inspection and copying within thirty days of service hereof at the office of Knobbe Martens Olson & Bear LLP, 550 West C Street, Suite 1200, San Diego, California 92101, or at such time and place as may be agreed upon between the parties. These requests are deemed continuing in nature, requiring amended or supplemental answers.

DEFINITIONS AND INSTRUCTIONS

Please use the following definitions for the purpose of responding to these Requests for Production of Documents and Things for Inspection and Copying:

1. The terms "Plaintiffs" and "LMA" shall refer to The Laryngeal Mask Company, Ltd. and LMA North America, Inc. and any present or former officer, director, employee, agent, attorney or other representative acting on their behalf, and shall include any predecessor, successor, parent, controlled, or affiliated companies, and any person or company assisting by agreement or otherwise in this lawsuit, and their agents, officers, employees, representatives, and attorneys.

2. As used herein, "AMBU," "Defendant," "You," and "Your" shall mean (a) Defendants AMBU A/S, AMBU INC., and AMBU LTD., their predecessor corporations, successor corporations, parent corporations, and each subsidiary, affiliated or related company; (b) each of their present or past directors, officers, employees, agents, consultants, accountants, representatives, attorneys and independent contractors which have contractual relations with them; and (c) any person acting or purporting to act or, at the time of the stated subject matter, was acting or purporting to act for or on behalf of AMBU or anyone under its control, direction or instruction.

3. The term "patent in suit" shall refer to U.S. Patent No. 7,156,100.

4. The term "the '100 Patent" shall refer to U.S. Patent No. 7,156,100.

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5. The term "First Answer" shall refer to Defendant Ambu Inc.'s Answer and Counterclaims (with caption) to Plaintiffs' First Amended Complaint for Patent Infringement filed on December 5, 2007.

6. The term "Second Answer" shall refer to Answer and Counterclaims (with caption) of Ambu A/S, Ambu Ltd., and Ambu Sdn. Bhd. to Plaintiffs' First Amended Complaint for Patent Infringement filed on January 30, 2008.

7. The term "First Counterclaim" shall refer to the counterclaim set forth in Paragraph 9 of Your first answer and Paragraph 12 of Your second answer.

8. The term "Second Counterclaim" shall refer to the counterclaim set forth in Paragraph 10 of Your first answer and Paragraph 13 of Your second answer.

9. As used herein, the term "Accused Product(s)" shall include, but is not limited to, AMBU's "Laryngeal Mask", AuraOnce, Aura40, AuraFlex and AuraStraight brands of laryngeal mask airway devices.

10. As used herein, the term "laryngeal mask airway device" shall include any artificial airway device having a mask or inflatable cuff designed for insertion into the throat of the patient so as to permit ventilation of the lungs.

11. As used herein, the word "document(s)" is used in its customary broad sense and includes all written, typed, printed, recorded or graphic statements, communications, electronically stored information, or other matter, stored or maintained in any medium, however produced or reproduced, and whether or not now in existence, in the possession, custody or control of AMBU, or otherwise known to AMBU, without limitation: writings; correspondence; literature; papers; memoranda; electronic mail or other electronic transmissions; studies; reports; notes; notations; diaries; messages; telegrams; books; invoices; letters; ledgers; drawings; proofs; photographs; displays; publications; advertisements; catalogs; brochures; pamphlets; labels; packaging; artwork; tear sheets; sketches; illustrative materials; magnetic recording tapes, microfilms, and other storage means by which information is retained in retrievable form; price lists; videotapes; models; films; recordings; contracts; purchase orders; all drafts of the foregoing; and any other

materials whether printed, typewritten, handwritten, recorded, or reproduced by any mechanical, electronic or magnetic process; including copies and reproductions of the foregoing upon which notations have been made which did not appear on the original, and all other materials within the scope of Fed. R. Civ. P. 34.

12. The term "person(s)" shall include natural persons, corporate or other business entities, and all other forms of legal entities, whether or not in the employ of any party. The acts and knowledge of a "person" are defined to include the acts and knowledge of that person's directors, officers, owners, members, employees, representatives, agents, and/or attorneys.

13. The terms "refer to," "relate to," "relating" and "relates" shall mean comprising, constituting, containing, embodying, identifying, stating, dealing with, directly or indirectly mentioning or describing, pertaining or referring to, being connected with, reflecting upon or resulting from the stated subject matter.

14. The terms "and" or "or" shall be construed disjunctively or conjunctively as necessary in order to bring within the scope of the request all documents and things which might otherwise be construed to be outside its scope.

15. The plural of any term shall be construed as the singular, and vice versa, as necessary an in order to bring within the scope of these Requests any information, documents, or things that might otherwise be construed to be outside their scope.

16. If any responsive document was, but no longer is, in your possession, custody, or control, state whether it has been lost, destroyed, transferred or is missing, or has otherwise been disposed of, and explain in each instance the circumstances surrounding the disposition of the document and the date it occurred.

17. With respect to a person, "identify" means to state the name, title and present address of the person, or if unknown, the last known address of such person.

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18. With respect to a document, "identify" means to state the document's date, title, author, addresses, copies' recipients, other persons who have read (or have been provided with) a copy, and to describe its character and substance sufficiently to make clear what the document is.

19. If you contend that any requested information is privileged or otherwise not subject to discovery, or if any information is withheld for any other reason, please state the following as to the withheld information:

a. the nature and date of the subject matter;

b. the author;

c. the person or persons to whom the subject matter was conveyed, either orally or in writing, together with their job title or position;

d. a sufficient description of the subject matter such that the Court will be able to rule on a motion to compel the withheld information;

e. the specific basis upon which the privilege is claimed; and

f. the Request to which each claim of privilege applies.

20. If you contend that any requested document is privileged or otherwise not subject to discovery, or if any document is withheld for any other reason, please state the following as to each such document:

a. the name of each signatory and the capacity in which each signed;

b. the date;

c. the name of each author and the capacity in which each was acting at the time he or she addressed or created the document;

d. the name of each addressee;

e. the name of each person copied on the document;

f. the subject matter;

g the specific grounds or reasons asserted for withholding the document; and

h. the present location of the document.

21. If any information is withheld in reliance on an asserted objection to a portion of a Request for Production of Documents, please produce information responsive to all other portions of the Request for Production of Documents to which no objection has been made.

22. These Requests for Production of Documents request responsive information in the possession, custody or control of the requested party or its attorneys, agents, or affiliated or related entities.

23. AMBU's obligations to respond to the following requests are continuing and the responses are to be supplemented to include subsequently acquired documents and things in accordance with the requirements of the Federal Rules of Civil Procedure.

REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS

REQUEST FOR PRODUCTION NO. 1:

Documents sufficient to identify each different Accused Product.

REQUEST FOR PRODUCTION NO. 2:

Documents sufficient to identify each different laryngeal mask airway device which has a variation in the thickness of the cuff wall that AMBU has distributed, imported, made, used, sold or offered for sale.

REQUEST FOR PRODUCTION NO. 3:

Documents sufficient to describe the structure of each different Accused Product.

REQUEST FOR PRODUCTION NO. 4:

Documents sufficient to describe the structure of each different laryngeal mask airway device which has a variation in the thickness of the cuff wall that AMBU has distributed, imported, made, used, sold or offered for sale.

REQUEST FOR PRODUCTION NO. 5:

All documents and things relating to the design or development of each different Accused Product.

REQUEST FOR PRODUCTION NO. 6:

All documents relating to any changes or modifications to the design of each different Accused product, including the reason for any such change or modification.

REQUEST FOR PRODUCTION NO. 7:

All communications between AMBU and any other person regarding the design of each different Accused Product.

REQUEST FOR PRODUCTION NO. 8:

All documents related to communications, meetings, discussions, or other interactions between AMBU and Dr. Archibald Brain, including interactions involving Mr. Lasse Petersen, including any notes or agreements, whether signed or unsigned.

REQUEST FOR PRODUCTION NO. 9:

All laryngeal mask airway devices used in meetings between AMBU and Dr. Brain.

REQUEST FOR PRODUCTION NO. 10:

All documents and things relating to the conception of each different Accused Product.

REQUEST FOR PRODUCTION NO. 11:

All documents and things relating to the reduction to practice of each different Accused Product.

REQUEST FOR PRODUCTION NO. 12:

Documents sufficient to determine the time periods over which Ambu designed, tested, developed, and manufactured each of its laryngeal mask airway products having a variation in the thickness of the cuff wall.

REQUEST FOR PRODUCTION NO. 13:

All documents related to the folding-over during insertion into a patient of the tip of the cuff of any AMBU laryngeal mask airway device, including AMBU's Standard™ laryngeal mask airway device.

REQUEST FOR PRODUCTION NO. 14:

All documents related to reinforcing the tip of the cuff of any of AMBU's laryngeal mask airway products.

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REQUEST FOR PRODUCTION NO. 15:

All documents related to changes in the design for any reinforcement of the tip of the cuff of AMBU's laryngeal mask airway devices and the reasons for any such design changes.

REQUEST FOR PRODUCTION NO. 16:

All documents related to any attempt by AMBU to design around the claims of the '100 patent.

REQUEST FOR PRODUCTION NO. 17:

All documents related to AMBU's decision to enter the market for laryngeal mask airway devices, including but not limited to all strategic plans for Ambu's entry into the market for laryngeal mask airway devices, all assessments of market needs, and all documents analyzing the features and benefits of reinforcing the tips of laryngeal mask airway devices and making such devices easier to insert in patients.

REQUEST FOR PRODUCTION NO. 18:

Documents sufficient to show the dates that the Accused Products were first imported into, distributed within, and sold in the United States.

REQUEST FOR PRODUCTION NO. 19:

Documents sufficient to show the dates that the Accused Products were first sold anywhere in the World.

REQUEST FOR PRODUCTION NO. 20:

Documents sufficient to show the dates that the Accused Products were first delivered to any customer or potential customer in the United States, whether such products were sold or otherwise distributed for use in patients.

REQUEST FOR PRODUCTION NO. 21:

All research and development documents, including, but not limited to, inventor notebooks, prototype drawings, product design files, lab reports, test data and clinical studies, reflecting any work on the design of each different Accused Product.

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REQUEST FOR PRODUCTION NO. 22:

All engineering drawings, manufacturing specifications, product specifications and design specifications for each different Accused Product.

REQUEST FOR PRODUCTION NO. 23:

All documents relating to any patent application describing or claiming any feature of each different Accused Product.

REQUEST FOR PRODUCTION NO. 24:

All documents relating to any issued patent describing or claiming any feature of each different Accused Product.

REQUEST FOR PRODUCTION NO. 25:

All documents and things relating to any perceived advantages or benefits of each different Accused Product, including, but not limited to, presentation materials, test results, reports, advertisements and marketing materials.

REQUEST FOR PRODUCTION NO. 26:

All documents relating to the marketing, sales, or distribution of any Accused Product, including sales representation training materials, promotional literature, and scripts.

REQUEST FOR PRODUCTION NO. 27:

All documents relating to complaints about laryngeal mask airway devices, including the sales, marketing, distribution, or performance of any laryngeal mask airway devices.

REQUEST FOR PRODUCTION NO. 28:

All documents relating to communications with doctors, hospitals, and GPOs regarding laryngeal mask airway devices.

REQUEST FOR PRODUCTION NO. 29:

Three (3) samples of each different Accused Product.

REQUEST FOR PRODUCTION NO. 30:

One (1) copy of each direction for use, other instructional documents, and any videos for each different Accused Product.

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REQUEST FOR PRODUCTION NO. 31:

One (1) copy of each advertisement, brochure, and other promotional material used in connection with the marketing, promotion or sale of each different Accused Product.

REQUEST FOR PRODUCTION NO. 32:

All documents and things relating to AMBU's decision to distribute, import, make, use, sell and offer to sell each different Accused Product.

REQUEST FOR PRODUCTION NO. 33:

All documents relating to any clinical testing or clinical evaluation of each different Accused Product, including, but not limited to, white papers and peer-reviewed publications.

REQUEST FOR PRODUCTION NO. 34:

All documents relating to any regulatory approval to market each different Accused Product.

REQUEST FOR PRODUCTION NO. 35:

All documents relating to the '100 Patent or U.S. Patent Application No. 09/412,954.

REQUEST FOR PRODUCTION NO. 36:

All documents and things constituting, evidencing or relating to prior art AMBU contends is relevant to the validity of any claim of the '100 Patent.

REQUEST FOR PRODUCTION NO. 37:

A sample of any prior art device AMBU contends is relevant to the validity of any claim of the '100 patent.

REQUEST FOR PRODUCTION NO. 38:

All documents and things referring to LMA.

REQUEST FOR PRODUCTION NO. 39:

All documents and things relating to any of LMA's laryngeal mask airway devices including, but not limited to, marketing studies and reports, product comparisons, consumer surveys and infringement studies.

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REQUEST FOR PRODUCTION NO. 40:

All documents related to any comparisons between Your Accused Products and LMA's Products.

REQUEST FOR PRODUCTION NO. 41:

All documents identifying competitors in the market for laryngeal mask airway devices or competition with respect to AMBU's Accused Products.

REQUEST FOR PRODUCTION NO. 42:

All documents related to any competitive analyses or comparisons of any Accused Product with any other product, including with respect to any LMA product.

REQUEST FOR PRODUCTION NO. 43:

All documents relating to any situation where You and another supplier competed for a sale of any laryngeal mask airway device or competed for a contract related to a sale of any laryngeal mask airway device, such as with respect to a Group Purchasing Organization ("GPO") contract.

REQUEST FOR PRODUCTION NO. 44:

All documents relating to Your efforts to compete against another supplier's laryngeal mask airway devices, including but not limited to, the manner in which You have promoted, marketed, or priced your products against LMA's or another supplier's products.

REQUEST FOR PRODUCTION NO. 45:

All documents relating to the pricing of laryngeal mask airway devices, including proposals, offers, or bids to GPOs for any Accused Product.

REQUEST FOR PRODUCTION NO. 46:

All documents that discuss, describe or analyze the reasons why or whether Your customers have purchased or have not purchased Your Accused Products.

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REQUEST FOR PRODUCTION NO. 47:

All documents that refer to, relate to, or constitute a criticism of LMA or its laryngeal mask airway devices, including, but not limited to, the quality of any LMA laryngeal mask airway device or the ability of LMA to manufacture, distribute or supply any of its laryngeal mask airway devices.

REQUEST FOR PRODUCTION NO. 48:

All documents that refer to, relate to, or constitute criticism of You or Your Accused Products, including, but not limited to, the quality of any such product or Your ability to manufacture, distribute, or supply such products.

REQUEST FOR PRODUCTION NO. 49:

All documents concerning customer satisfaction reports or customer comments relating to the Accused Products.

REQUEST FOR PRODUCTION NO. 50:

All management presentations, including but not limited to those made to AMBU's Board of Directors, investors, and financial institutions (including without limitation ABN Amro Bank, ABG Sundal Collier (Malene Brodenberg), SEB Enskilde (Niels Granhom-Leth), Gudme Raaschou Bank (Brian Rathje), FIH Capital Markets/Kaupthing Bank (Thomas Winther Sorensen)) concerning LMA, competition with LMA, competition with other suppliers of laryngeal mask airway devices, sales, marketing, and pricing strategies for AMBU's laryngeal mask airway devices, the '100 patent, and U.S. Patent Application No. 09/412,954.

REQUEST FOR PRODUCTION NO. 51:

All stock exchange and press releases relating to laryngeal mask airway devices and documents relating to those releases.

REQUEST FOR PRODUCTION NO. 52:

All documents related to the market shares of suppliers of laryngeal mask airway devices, including sales by third parties of such devices.

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REQUEST FOR PRODUCTION NO. 53:

Documents sufficient to show AMBU's document retention and destruction policies or procedures, including retention of electronic documents and email.

REQUEST FOR PRODUCTION NO. 54:

All documents including, but not limited to, any opinion of counsel, relating to the scope, validity, infringement, noninfringement, enforceability or unenforceability of the '100 Patent or the patent claims therein.

REQUEST FOR PRODUCTION NO. 55:

All documents and things that form the bases for, in whole or in part, or that were considered in connection with any opinion of counsel relating to the scope, validity, infringement, noninfringement, enforceability or unenforceability of the '100 Patent or the patent claims therein.

REQUEST FOR PRODUCTION NO. 56:

All documents that relate to any prior art search or investigation concerning the '100 Patent or the subject matter claimed therein.

REQUEST FOR PRODUCTION NO. 57:

All documents and things that relate to AMBU's first awareness or knowledge of the '100 Patent.

REQUEST FOR PRODUCTION NO. 58:

All documents and things that relate to AMBU's awareness or knowledge of United States Patent Application No. 09/412,954.

REQUEST FOR PRODUCTION NO. 59:

All documents relating to AMBU's litigation against LMA in Europe.

REQUEST FOR PRODUCTION NO. 60:

All documents and things upon which AMBU intends to rely in defense to LMA's allegation that AMBU's infringement of the '100 Patent has been willful.

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REQUEST FOR PRODUCTION NO. 61:

All documents identified or requested to be identified in response to LMA's Interrogatories to AMBU.

REQUEST FOR PRODUCTION NO. 62:

All documents and things upon which AMBU relied or referred to in preparing its responses to LMA's Interrogatories.

REQUEST FOR PRODUCTION NO. 63:

Organizational charts or other documents sufficient to show the identity of all persons responsible for research, development and design of each different Accused Product.

REQUEST FOR PRODUCTION NO. 64:

Organizational charts or other documents sufficient to show the identity of all persons responsible for the sales and marketing in the United States of each different Accused Product.

REQUEST FOR PRODUCTION NO. 65:

All documents relating to any monetary evaluation of the '100 Patent conducted by or at the direction of AMBU, including, but not limited to, any determination of the appropriate royalty rate for using the inventions claimed in the '100 Patent.

REQUEST FOR PRODUCTION NO. 66:

All marketing or business plans relating to each different Accused Product.

REQUEST FOR PRODUCTION NO. 67:

All documents reflecting plans, projections, or forecasts for sales of the different Accused products.

REQUEST FOR PRODUCTION NO. 68:

Documents sufficient to show the sales volume of each different Accused Product in the United States.

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REQUEST FOR PRODUCTION NO. 69:

Documents sufficient to identify all customers of each different Accused Product in the United States and each customer order, including date of the order, units ordered and the unit price.

REQUEST FOR PRODUCTION NO. 70:

All documents and things that support or otherwise form the bases for, in whole or in part, the affirmative defense stated on Paragraph 25 of Your First Answer and Paragraph 26 of Your Second Answer that AMBU has not infringed and does not infringe, either directly, contributively, or by inducement, any valid claim of the '100 Patent, either literally or under the doctrine of equivalents.

REQUEST FOR PRODUCTION NO. 71:

All documents and things that support or otherwise form the bases for, in whole or in part, the affirmative defense stated in Paragraph 26 of Your First Answer and Paragraph 27 of Your Second Answer that the '100 Patent is invalid for failure to meet the requirements of one or more sections of Title 35, United States Code, and/or Title 37, Code of Federal Regulations, including but not limited to one or more of 35 U.S.C. §§ 102 and 103.

REQUEST FOR PRODUCTION NO. 72:

All documents and things that support or otherwise form the bases for, in whole or in part, AMBU's First Counterclaim that AMBU has not infringed and does not infringe, either directly, contributively, or by inducement, any valid claim of the '100 Patent, either literally or under the doctrine of equivalents.

REQUEST FOR PRODUCTION NO. 73:

All documents and things that support or otherwise form the bases for, in whole or in part, AMBU's Second Counterclaim that the '100 Patent is invalid for failure to meet the requirements of one or more sections of Title 35, United States Code, and/or Title 37, Code of Federal Regulations, including but not limited to one or more of 35 U.S.C. §§ 102 and 103.

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REQUEST FOR PRODUCTION NO. 74:

Documents sufficient to determine the following on a monthly basis (or the next shortest time period tracked by AMBU – e.g. quarterly) for sales in the United States of each different laryngeal mask airway device which has a variation in the thickness of the cuff wall, including, but not limited to the Accused Products:

(a) Gross Revenue and Net Revenue, by customer and product, listing the amount for all deductions required to reconcile Gross and Net Revenues;

(b) Average sales price;

(c) Total quantity of units sold and the total quantity sold, net of any returns by customers, by product;

(d) Total quantity of units produced; and

(e) Cost of goods sold on a per product basis, including but not limited to: (i) direct labor and material costs; (ii) indirect labor and material costs; (iii) manufacturing overhead costs; (iv) standard costs and any associated variances; (v) actual total cost and variances from standard cost; (vi) gross profits, gross margins, or standard margins on a per product basis; and (vii) all costs, other than manufacturing costs, on a per product basis, including but not limited to: (A) commissions and other selling expenses; (B) general and administrative expenses; (C) engineering, research, and development expenses; and (D) net income or net profit before taxes on a per product basis.

REQUEST FOR PRODUCTION NO. 75:

Documents sufficient to describe Your methods for accounting for revenues, costs and profits.

REQUEST FOR PRODUCTION NO. 76:

Documents sufficient to explain all acronyms, abbreviations and short forms of labels used on Your financial, marketing and sales documents.

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REQUEST FOR PRODUCTION NO. 77:

All AMBU's annual reports, required financial filings and other financial statements, including statements of operations, profit and loss statements, income statements, balance sheets, statements of changes in retained earnings, internal management reports and notes thereto, whether the notes are for internal or external reporting purposes.

REQUEST FOR PRODUCTION NO. 78:

Documents sufficient to show all corporate relationships between and among AMBU's subsidiaries, affiliates, and other related entities, including stock ownership interest and control of any other entity.

REQUEST FOR PRODUCTION NO. 79:

All documents identified in AMBU's Fed. R. Civ. P. 26(a)(a) Initial Disclosure Statement served on May 28, 2008, including but not limited to the subjects and custodians described in section 1 and the categories described in section 2.

REQUEST FOR PRODUCTION NO. 80:

All operating agreements, articles of incorporation, bylaws, shareholder agreements, member agreements, voting agreements, or any other documents that govern the internal functions of AMBU.

REQUEST FOR PRODUCTION NO. 81:

Documents sufficient to show the organizational structure of AMBU A/S, including but not limited to charts or lists of AMBU A/S's managers, principals, officers, directors, board members, employees, consultants, contractors, counsel or attorneys, or any organizational chart(s) that include(s) AMBU A/S.

REQUEST FOR PRODUCTION NO. 82:

Documents sufficient to show the organizational structure of AMBU INC., including but not limited to charts or lists of AMBU INC.'s managers, principals, officers, directors, board members, employees, consultants, contractors, counsel or attorneys, or any organizational chart(s) that include(s) AMBU INC.

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REQUEST FOR PRODUCTION NO. 83:

Documents sufficient to show the organizational structure of AMBU LTD., including but not limited to charts or lists of AMBU LTD.'s managers, principals, officers, directors, board members, employees, consultants, contractors, counsel or attorneys, or any organizational chart(s) that include(s) AMBU LTD.

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: May 30, 2008

By: _____
John B. Sganga
Frederick S. Berretta
Joshua J. Stowell

Attorneys for Plaintiffs
THE LARYNGEAL MASK COMPANY LTD.
and LMA NORTH AMERICA, INC.

CERTIFICATE OF SERVICE

I am a citizen of the United States of America and I am employed in San Diego, California. I am over the age of 18 and not a party to the within action. My business address is 550 West C Street, San Diego, California 92101. I served the within **PLAINTIFFS' FIRST SET OF REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS (NOS. 1 - 83)** on the parties or their counsel shown below, via U.S. Mail, addressing it as follows:

Darryl M. Woo
FENWICK & WEST LLP
555 California Street, 12th Floor
San Francisco CA 94104
dwoo@fenwick.com
T: 415-875-2300
F: 415-281-1350

I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

Dated: May 30, 2008

Megan Ptacin

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053008

Exhibit D

LMA™ AIRWAY INSTRUCTION MANUAL

Revised 2005

LMA | ProSeal™

LMA | Unique™ SINGLE USE

LMA | Classic™

LMA | Flexible™ SINGLE USE

&

LMA | Flexible™

LMA | Classic™

LMA | Flexible™

LMA | ProSeal™

LMA | Unique™ SINGLE USE

LMA | Flexible™ SINGLE USE

INSTRUCTION MANUAL

Revised 2005

Manufactured by:
LMA™
The Laryngeal Mask Company Limited

Distributed by:
LMA™
LMA North America, Inc.
www.lmana.com
San Diego, CA 92122
(800) 788-7999
P/N: 3000327-1-04/05

LMA™ Airway Summary

LMA™ Airway *(Year of U.S. Introduction)*	Primary Use	PPV	Spontaneous breathing	Reusable (Y/N)	Adult Sizes	Pediatric Sizes	Ease of Intubation	Use with MRI
LMA Classic™ *(1992)*	Routine GA cases	Up to 20 cm H_2O	+++	Y	4, 5, 6	1, 1½, 2, 2½, 3	++	++
LMA ProSeal™ *(2000)*	Cases needing higher seal pressures, especially with PPV Cases where access to GI tract is desired	Up to 30 cm H_2O	++	Y	4, 5	1½, 2, 2½, 3	+	+
LMA Flexible™ *(1996)*	Head & neck cases, especially eyes, ears, nose & throat	Up to 20 cm H_2O	+	Y	4, 5, 6	2, 2½, 3	–	+
Single Use LMA Flexible™ *(2004)*	Head & neck cases, especially eyes, ears, nose & throat	Up to 20 cm H_2O	+	N	4, 5	2, 2½, 3	–	+
LMA Unique™ *(1997)*	Routine GA cases Stock crash carts for rescue airway	Up to 20 cm H_2O	+++	N	4, 5	2, 2½, 3	++	++
LMA Fastrach™* *(1998)*	Facilitate intubation	Up to 20 cm H_2O	++	Y	4, 5	3	+++	–

(–) = Not compatible
\+ = Compatible
++ = Recommended
+++ = Optimal
GA = General anesthesia
* Detailed instructions in a separate manual

TABLE OF CONTENTS

Manufacturer's Warranty

The Laryngeal Mask Company Limited warrants the LMA™ airway products against faulty materials or manufacturing defects. The reusable LMA™ airways are warranted for forty (40) uses or a period of one (1) year from date of invoice, whichever comes first, provided that the product is used in accordance with the procedures set forth in the instruction manual. A completed LMA™ airway record card or log sheet recording uses and the LMA™ airway must accompany any return for evaluation of a manufacturing defect. Single-use products are warranted against faulty materials or manufacturing defects at time of delivery to customer. Warranty applicable only if purchased from an authorized distributor. THE LARYNGEAL MASK COMPANY LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

CAUTION: *Federal law restricts this device to sale by or on the order of a practitioner licensed by state law to use such device.*

DEVICE DESCRIPTION 1

The LMA™ airway is a supraglottic airway management device.[1] Since its commercial introduction in 1988, the LMA™ airway has been used in over 200 million patients for routine and emergency procedures.

The LMA™ system of products includes 6 airway devices and various accessories, all of which are latex-free. A summary table describing the airway devices is provided on the inside front cover of the manual. This manual covers 5 of the airway devices: the LMA ProSeal™, the LMA Unique™, the LMA Classic™, the LMA Flexible™ and the single use LMA Flexible™. An additional LMA™ airway designed to facilitate endotracheal intubation, the LMA Fastrach™, is covered in another instruction manual.

All LMA™ airway devices have three main components: airway tube, mask, and inflation line (Figure 1). The airway tube has a standard 15 mm connector. The mask is designed to conform to the contours of the hypopharynx with its lumen facing the laryngeal opening.

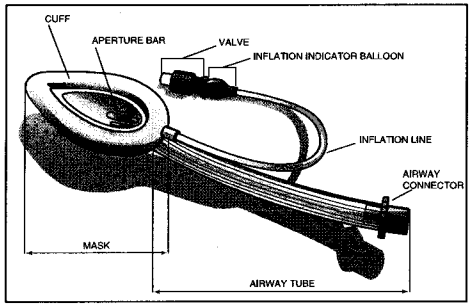


Fig. 1: The components of the LMA™ *airway.*

The LMA™ airway is designed to be a minimally-stimulating device. When fully inserted using the recommended insertion technique, the distal tip of the LMA™ cuff presses against the upper esophageal sphincter. Its sides face into the pyriform fossae and the upper border rests against the base of the tongue (Figure 2).

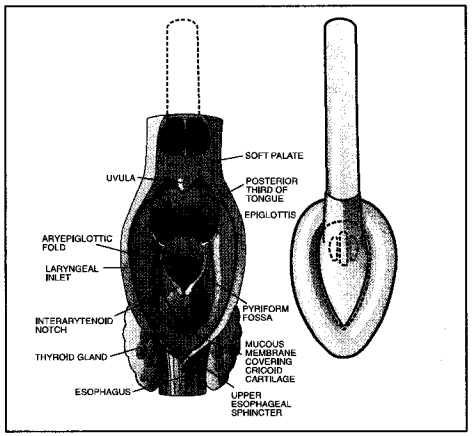


Fig. 2: Dorsal view of the LMA™ *cuff showing position in relation to pharyngeal anatomy.*

The LMA Classic™, LMA ProSeal™ and LMA Flexible™ are reusable devices, made primarily of medical-grade silicone. The Laryngeal Mask Company Limited recommends that the reusable LMA™ airways be used a maximum of 40 times, before being discarded. The LMA Unique™ and the single use LMA Flexible™ are sterile, single use devices, made primarily of medical-grade PVC.

LMA Classic™/LMA Unique™

The LMA Classic™ is the original LMA™ airway, with the basic features and components as described above. The single use LMA Unique™ is the disposable version of the LMA Classic™.

LMA ProSeal™

The LMA ProSeal™ is an advanced form of LMA™ airway that may be used for the same indications as the LMA Classic™, but also has features that provide more patient management options and may expand the procedures where the device can be used. While the LMA Classic™ may be used with low-pressure positive pressure ventilation (PPV), the LMA ProSeal™ has been specifically designed for use with PPV with and without muscle relaxants at higher airway pressures. The LMA ProSeal™ does not protect the airway from the effects of regurgitation and aspiration.

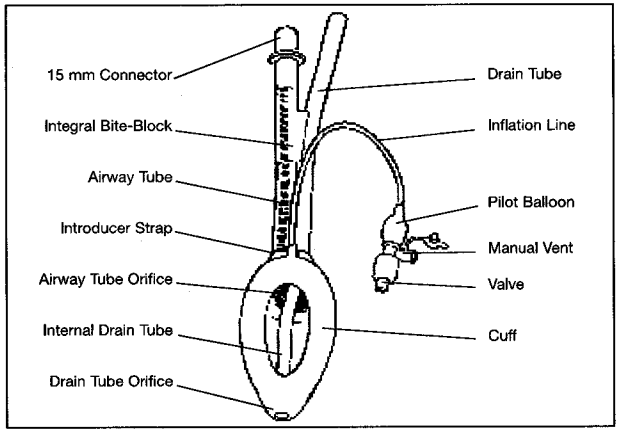


Fig. 3: The components of the LMA ProSeal™.

The cuff is made of a softer material than the LMA Classic™ and larger sizes also have a rear cuff which helps to increase the seal. Attached to the valve and inflation balloon of the inflation line is a red manual vent, which prevents expansion of the cuff when left open during steam autoclaving. Within the mask, a drain tube provides a conduit that communicates with the upper esophageal sphincter. The airway tube is wire-reinforced to resist kinking.

The removable LMA ProSeal™ Introducer is available to aid insertion of the LMA ProSeal™ without the need to place fingers in the mouth. A dedicated deflation device (LMA ProSeal™ Cuff-Deflator) is also available to help obtain complete deflation of the LMA ProSeal™ for optimum insertion and positioning within the patient.

In addition to the well known characteristics of the LMA Classic™, the LMA ProSeal™ design provides the following features:

- A softer cuff material, deeper mask bowl and special cuff shape allows a higher seal than the LMA Classic™ for a given intracuff pressure with the adult sizes.[2,3,4]
- A drain tube communicates with the upper esophageal sphincter and permits venting of the stomach and blind insertion of standard gastric tubes, in any patient position, without the need to use Magill's forceps.
- A double tube arrangement reduces the likelihood of device rotation; the revised cuff profile, together with the two tubes, results in the device being more securely anchored in place.
- A built-in bite-block reduces the possibility of airway obstruction or tube damage.
- A strap for the LMA ProSeal™ Introducer also accommodates the index finger or thumb for manual insertion.
- The position of the drain tube inside the cuff is designed to prevent the epiglottis from occluding the airway tube. This eliminates the need for aperture bars.

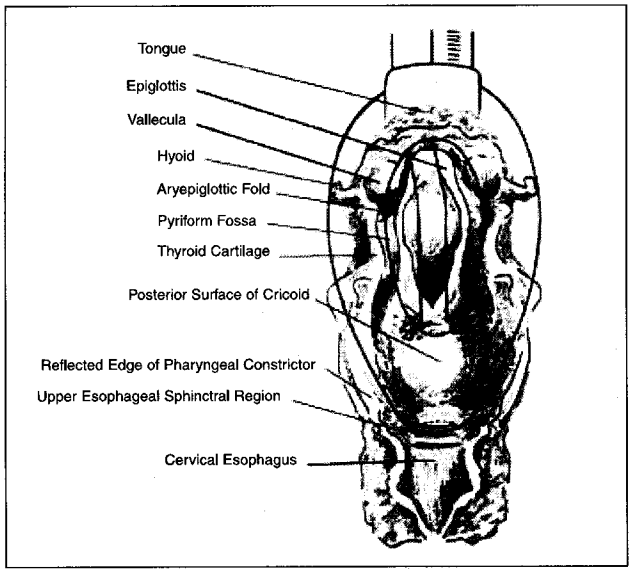


Fig. 4: Dorsal view of the LMA ProSeal™ *cuff showing position in relation to pharyngeal anatomy.*

LMA Flexible™ / Single Use LMA Flexible™

The LMA Flexible™ has a wire-reinforced, flexible airway tube that allows it to be positioned away from the surgical field. The single use LMA Flexible™ is the disposable version of this device. It is particularly useful in procedures where the surgeon and the anesthesia provider are competing for access, such as head and neck procedures.

The flexibility of the airway tube provides an easy connection at any angle from the mouth and allows the tube to be repositioned from side to side during the surgical procedure without loss of seal of the cuff against the larynx. The airway tube also resists kinking when, under normal conditions, it is flexed or compressed against a rigid mouth gag. The reinforced, flexible airway tube does not, however, offer resistance to occlusion by biting.

The airway tubes of the different LMA™ airways vary in length and diameter. Table 1 (in the back of the manual) shows the different dimensions for the available sizes of each LMA™ airway type.

2 INDICATIONS

The LMA™ airway is indicated for use as an alternative to the face mask for achieving and maintaining control of the airway during routine and emergency anesthetic procedures.

The LMA™ airway is not indicated for use as a replacement for the endotracheal tube, and is best suited for use in elective surgical procedures where tracheal intubation is not necessary.

The LMA™ airway is also indicated in a known or unexpected difficult airway situation.

The LMA™ airway is also indicated as a method of establishing a clear airway during resuscitation in the profoundly unconscious patient with absent glossopharyngeal and laryngeal reflexes who may need artificial ventilation. In these cases, the LMA™ airway should be used only when tracheal intubation is not possible.

3 CONTRAINDICATIONS

Due to the potential risk of regurgitation and aspiration, do not use the LMA™ airway as a substitute for an endotracheal tube in the following elective or difficult airway patients on a non-emergency pathway:

- Patients who have not fasted, including patients whose fasting cannot be confirmed.
- Patients who are grossly or morbidly obese, more than 14 weeks pregnant or those with multiple or massive injury, acute abdominal or thoracic injury, any condition associated with delayed gastric emptying, or using opiate medication prior to fasting.

The LMA™ airway is also contraindicated in:

- Patients with fixed decreased pulmonary compliance, such as patients with pulmonary fibrosis, because the LMA™ airway forms a low-pressure seal around the larynx.
- Patients where the peak airway inspiratory pressures are anticipated to exceed:
  - 20 cm H_2O with LMA Classic™, LMA Unique™, or LMA Flexible™ / single use LMA Flexible™.
  - 30 cm H_2O with LMA ProSeal™.
- Adult patients who are unable to understand instructions or cannot adequately answer questions regarding their medical history, since such patients may be contraindicated for LMA™ airway use.

When used in the profoundly unresponsive patient in need of resuscitation or in a difficult airway patient on an emergency pathway (i.e.,"cannot intubate, cannot ventilate"), the risk of regurgitation and aspiration must be weighed against the potential benefit of establishing an airway. The LMA™ airway should not be used in the resuscitation or emergency situation in patients who are not profoundly unconscious and who may resist LMA™ airway insertion.

WARNINGS 4

Throughout this instruction manual, appropriate warnings are given describing potential safety hazards associated with use of the LMA™ airway, limitations during use, and steps that should be taken should they occur. The user should be familiar with the following warnings prior to use of the LMA™ airway.

Preparation for use

- All reusable LMA™ airways (LMA Classic™, LMA ProSeal™, and the LMA Flexible™) are delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use.
- Do not attempt to clean and reuse the single use LMA Unique™ or single use LMA Flexible™.
- Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilize reusable LMA™ airways. Such substances are absorbed by the LMA™ airway, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use an LMA™ airway that has been exposed to any of these substances.
- Failure to properly clean, rinse, and dry a reusable LMA™ airway may result in retention of potentially hazardous residues or inadequate sterilization.
- All of the non-clinical tests described in this manual must be conducted before each use of any LMA™ airway. Failure of any one test indicates that the device has passed its useful life and should be replaced.
- Do not use the LMA™ airway or any of the accessories if they are damaged in any way.
- Do not use the LMA™ airway if the inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.
- Use of an LMA ProSeal™ with a collapsed or occluded drain tube may prevent venting of the stomach or insertion of a gastric tube and may permit inflation of the stomach and possible regurgitation. Use of a perforated or torn drain tube may prevent the LMA ProSeal™ from being inflated or allow for escape of anesthetic gases.

Insertion

- Make sure the LMA ProSeal™ red manual vent is closed during clinical use to prevent deflation of the cuff.
- Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.
- To avoid trauma, force should not be used at any time during insertion of the LMA™ airway or insertion of a gastric tube through the LMA ProSeal™ drain tube.
- Never overinflate the cuff after insertion.
- Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.
- Use of a bite-block reduces the possibility of the danger of airway obstruction or tube damage. A bite-block should be used with all LMA™ airways and kept in place until LMA™ airway removal.

- An incorrectly placed mask may result in an unreliable or obstructed airway or failure of the LMA ProSeal™ drain tube to channel fluids or gases from the stomach and may increase the likelihood of gastric insufflation if used with PPV. Always check for proper placement after insertion.

Usage

- The LMA™ airway does not protect the patient from the effects of regurgitation and aspiration.
- Should the LMA™ airway be used in a fasted patient who is at risk of retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed. Examples of conditions where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.
- In patients with severe oropharyngeal trauma, the device should only be used when all other attempts to establish an airway have failed.
- If airway problems persist or ventilation is inadequate, the LMA™ airway should be removed and an airway established by some other means.
- The presence of a gastric tube does not rule out the possibility of regurgitation and may even make regurgitation more likely because the gastric tube may make the lower esophageal sphincter incompetent.
- Do not attempt to pass a gastric tube through the LMA ProSeal™ drain tube in the presence of known or suspected esophageal pathology.
- To prevent injury to the upper esophageal sphincter, do not apply suction directly to the end of the LMA ProSeal™ drain tube.
- The effects of performing magnetic resonance imaging (MRI) procedures using LMA™ airways and MR systems with static magnetic fields greater than 1.5 Tesla and other conditions have not been tested.
- The LMA ProSeal™, LMA Flexible™, and single use LMA Flexible™ airways exhibit magnetic field interactions with respect to translational force and torque during exposure to a shielded 1.5 Tesla MR system (maximum spatial gradient, 450 gauss/cm). However, when these devices are properly positioned and adhesive tape or other similar dressing is used to retain placement, there is no additional risk to the patient with regard to movement or dislodgment using a shielded MR system with static magnetic field of 1.5 Tesla or less. Thus,when used with MRI, care should be taken to monitor the patient carefully to assure that correct positioning of the LMA™ airway tube is maintained.

This manual contains numerous precautionary statements regarding the special care to be exercised for the safe and effective use of the LMA™ airway. The user and others involved in the preparation for use of the device should be familiar with and adhere to these instructions.

Preparation for use

- Careful handling is essential. The LMA™ airways are made of medical-grade silicone or medical-grade PVC which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.
- For reusable LMA™ aiways, do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.
- Make sure the LMA ProSeal™ manual vent is closed during cleaning to prevent exposure of the valve to any cleaning solution.
- Any air or moisture left in the cuff of the LMA Classic™, reusable LMA Flexible™ or LMA ProSeal™ without manual vent will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.
- Make sure the LMA ProSeal™ manual vent is open during sterilization to prevent herniation of the cuff.
- The integrity of the reusable LMA™ airway materials may be adversely affected by exceeding sterilization temperatures of 275°F or 135°C.
- Gloves should be worn during preparation and insertion to minimize contamination of the device.

Usage

- MRI artifacts for the LMA™ airways have been characterized using a 1.5 Tesla MR system and various pulse sequences. Based on this information, MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the LMA ProSeal™, LMA Flexible™ or single use LMA Flexible™. The valve component located at the end of the inflation line should also be directed away from the area of interest to avoid artifacts.
- The need for instrumentation should be carefully considered and evaluated prior to insertion of an LMA Flexible™ / single use LMA Flexible™. If the need for instruments that cannot be passed through the device is anticipated, the use of another LMA™ airway or an alternate method of airway management should be considered.

6 ADVERSE EFFECTS

Both minor adverse effects (e.g., sore throat) and major adverse effects (e.g., aspiration) following use of LMA™ airways have been reported in the published literature.[5] Review of published literature shows the incidence of aspiration with the LMA™ airway is low (0.012%), with the main causes being inappropriate patient selection and inadequate depth of anesthesia.[5]

The incidence of sore throat following LMA™ airway use is approximately 13%, and is usually mild and short-lived[5]; however, severe or prolonged sore throat, sometimes accompanied by dysphagia and tissue burns, has been reported in patients in whom an improperly cleaned or sterilized reusable mask has been used.

Infrequent neurovascular events reported with LMA™ airway use include cases of hypoglossal nerve injury, tongue numbness secondary to lingual nerve injury, tongue cyanosis, tongue macroglossia, recurrent laryngeal nerve injury, and vocal cord paralysis. These complications are most likely the result of malposition or excessive intracuff pressure, causing compression of nerves and/or blood vessels. Cuff malposition or excessive cuff pressure can be exacerbated by incorrect mask size, prolonged surgery, and use of nitrous oxide.

Adverse events reported with LMA™ airway use include airway obstruction, arytenoid dislocation, aspiration, bleeding, breath holding, bronchospasm, coughing, dental/denture damage, dry mouth/throat, dysarthria, dysphagia, dysphonia, dysrhythmia, ear pain, gagging, gastric dilatation/insufflation/rupture, glottic closure, head and neck edema, hearing impairment, hiccup, hoarseness, hypersalivation, hypoglossal nerve paralysis, hypoxia, laryngeal hematoma, laryngeal spasm, lingual nerve paralysis, mouth ulcer, myocardial ischemia, nausea, parotid gland swelling, pharyngeal dysesthesia, pharyngeal ulcer, pulmonary edema, recurrent laryngeal nerve injury, regurgitation, retching, sore jaw, sore mouth, sore throat, stridor, submandibular gland swelling, temporomandibular joint dislocation, tissue trauma (epiglottis, larynx, lip, mouth, posterior pharyngeal wall, soft palate, uvula, tonsils), tongue cyanosis, tongue macroglossia, vocal cord paralysis, and vomiting.

PREPARATION FOR USE 7

With proper cleaning, sterilization, and handling, the reusable LMA™ airways can be used a maximum of 40 times. Proper cleaning and sterilization of the LMA™ airways are essential to ensure continued safe usage up to 40 times.

WARNING: *All reusable* LMA™ *airways* (LMA Classic™, LMA ProSeal™, *and the (reusable)* LMA Flexible™) *are delivered non-sterile and must be cleaned and sterilized before initial use and before each subsequent use. The packaging cannot withstand the high temperatures of autoclaving and should be discarded before sterilization.*

CAUTION: *Careful handling is essential. The* LMA™ *airways are made of medical-grade silicone or medical-grade PVC which can be torn or perforated. Avoid contact with sharp or pointed objects at all times.*

WARNING: *Do not attempt to clean and reuse a single use* LMA Unique™ *or single use* LMA Flexible™.

The LMA™ airway accessories, i.e., the LMA™ Cuff-Deflator, LMA ProSeal™ Introducer and LMA ProSeal™ Cuff-Deflator, should be cleaned and sterilized in the same manner as the LMA™ airways.

7.1 Cleaning reusable LMA™ airways

Thoroughly wash the device in warm water using a dilute (8-10% v/v) sodium bicarbonate/water solution until all visible foreign matter is removed. A 10% sodium bicarbonate solution can be prepared by mixing 1 cup of baking soda with 10 cups of water.

Mild detergents or enzymatic cleaning agents may be used in accordance with the manufacturer's instructions. The cleaners must not contain skin or mucous membrane irritants. A specific cleaner found to be compatible with LMA™ airway use is Endozime® (Ruhof, Valley Stream, NY).

WARNING: *Do not use germicides, disinfectants, or chemical agents such as glutaraldehyde (Cidex®), ethylene oxide, phenol-based cleaners, iodine-containing cleaners or quaternary ammonium compounds to clean or sterilize the* LMA™ *airway. Such substances are absorbed by the materials, resulting in exposure of the patient to potentially severe tissue burns and possible deterioration of the device. Do not use an* LMA™ *airway that has been exposed to any of these substances.*

CAUTION: *For reusable* LMA™ *airways, do not expose the valve (the white plastic piece protruding from the blue inflation balloon) to any cleaning solution as it may cause premature valve failure.*

If moisture is noticed in the valve, tap against a towel to remove excess moisture.

7.1.1 Cleaning the LMA Classic™ and (reusable) LMA Flexible™

Clean the airway tube using a small soft bristle brush approximately 1/2 inch in diameter. Gently insert the brush through the LMA Classic™ or (reusable) LMA Flexible™ aperture bars into the airway tube, taking care not to damage the bars.

Thoroughly rinse the cuff and tube in warm running tap water to remove cleaning residues. Carefully inspect to ensure that all visible foreign matter has been removed.

Repeat the above as necessary.

7.1.2 Additional instructions for cleaning the LMA ProSeal™

When washing the LMA ProSeal™, the red manual vent should be in the closed position (Figure 5) to prevent exposure of the valve to any cleaning solution. If moisture is noticed, the red manual vent should be opened and tapped against a towel to remove the excess moisture.

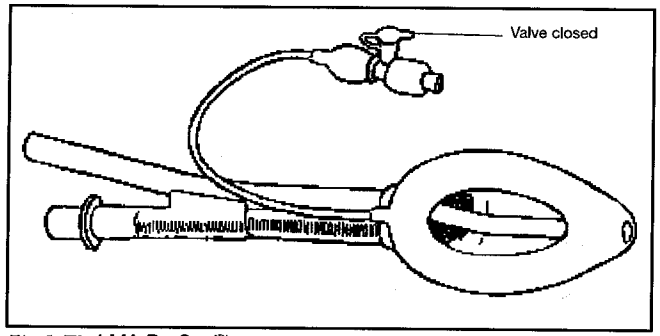


Fig. 5: The LMA ProSeal™ *manual vent in the closed position.*

CAUTION: *Make sure the* LMA ProSeal™ *manual vent is closed during cleaning to prevent exposure of the valve to any cleaning solution.*

When cleaning and rinsing the LMA ProSeal™, ensure the areas behind the Introducer strap and under the internal drain tube are clean. Clean the drain tube using a small soft bristle brush approximately 1/4 in or 6 mm in diameter for adult size devices (available from LMA North America, Inc.). Gently insert the brush through the front of the mask, taking care not to damage the drain tube.

7.2 Sterilization of reusable LMA™ airways

Steam autoclaving is the only recommended method for sterilization. Adherence to the following procedure is essential to ensure sterilization without damage:

7.2.1 Sterilization of the reusable: LMA Classic™ LMA Flexible™ and LMA ProSeal™ without manual vent

For the LMA Classic™, LMA Flexible™ and LMA ProSeal™ without manual vent, immediately prior to steam autoclaving, deflate the cuff, pulling the syringe backward to obtain a vacuum in the cuff.

For complete deflation, it is recommended that LMA™ Cuff-Deflator or LMA ProSeal™ Cuff-Deflator (available from LMA North America, Inc.) be used for this purpose. Ensure that both the syringe used to deflate the cuff and the valve are dry.

Do not use excessive force when inserting the syringe into the valve port. Remove the syringe from the valve port before autoclaving to avoid damage to the valve.

If the cuff of a deflated LMA Classic™, LMA Flexible™ or LMA ProSeal™ without manual vent immediately and spontaneously re-inflates after the syringe has been removed, do not autoclave or re-use the mask. This indicates the presence of a defective device. It is normal, however, for the cuff to re-inflate slowly over a period of several hours as the silicone rubber material is gas permeable.

CAUTION: *Any air or moisture left in the cuff of* LMA Classic™, LMA Flexible™ *or* LMA ProSeal™ *without manual vent will expand at the high temperatures and low pressures of the autoclave, causing irreparable damage (herniation and/or rupture) to the cuff and/or inflation balloon.*

7.2.2 Sterilization of the LMA ProSeal™ with manual vent

For the LMA ProSeal™, it is not necessary to deflate the cuff prior to steam autoclaving, so it is normal for the LMA ProSeal™ to be inflated upon removal from the autoclave, provided the manual vent is in the open position.

CAUTION: *Make sure the* LMA ProSeal™ *manual vent is open during sterilization to prevent herniation of the cuff (Fig. 6).*

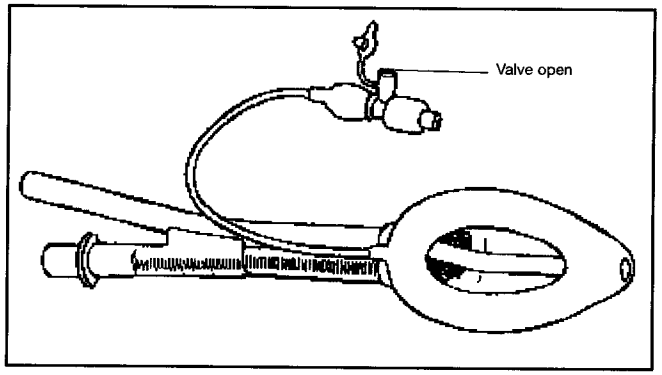


Fig. 6: The LMA ProSeal™ *manual vent in the open position.*

7.3 Autoclave settings

Steam autoclave following the recommendations of the institution or the autoclave manufacturer. All steam autoclave cycles typically used for porous items are acceptable, provided the maximum temperature does not exceed 275°F (135°C) (Table 2).

CAUTION: *The integrity of the* LMA™ *airway materials may be adversely affected by exceeding 275°F or 135°C.*

Table 2: Minimum Exposure Times

Steam Sterilization 270° – 275° F (132° – 135° C)

AUTOCLAVE	WRAPPED	UNWRAPPED (FLASH)
Gravity	10-15 min	10 min*
Prevacuum	3-4 min	4 min*

**Mixed porous and nonporous items*
Reference: AAMI Standards and Recommended Practices[6]

Autoclaves vary in design and performance characteristics. Cycle parameters should always be verified against the autoclave manufacturer's written instructions for the specific autoclave and load configuration being used.

Healthcare facility personnel are responsible for adhering to the processes specified and validated in their facility and for maintaining process control. Failure to do so may invalidate the healthcare facility's sterilization process.

After autoclaving allow the LMA™ airway to cool to room temperature before use.

7.4 Special considerations

The World Health Organization (WHO) guidelines and published literature[7,8] indicate that the LMA™ airway cleaning and sterilization procedures outlined above are sufficient for inactivation of conventional pathogens (i.e., bacteria, fungi, and viruses). In patients known or suspected to have a transmissible spongiform encephalopathy, it is recommended that institutions follow WHO guidelines[7] by destroying rather than reusing LMA™ airways after use, or use a disposable LMA™ airway.

The WHO also provides guidelines for institutions wishing to follow high level decontamination protocols for reusable medical devices. Testing has been performed to validate that LMA™ airways can withstand 40 autoclave cycles with up to a 20 minute exposure time. Note that all cautions and warnings regarding cleaning solutions must still be followed (e.g., do not clean with chemical agents).

7.5 Performance tests

All of the non-clinical tests described below must be conducted before each use of the device. The performance tests should be conducted in an area and in a manner consistent with accepted medical practice that minimizes contamination of the LMA™ airway before insertion.

WARNING: Do not use the LMA™ *airway or any of the accessories if damaged in any way.*

WARNING: Failure of any one test indicates that the device has passed its useful life and should be replaced.

CAUTION: Gloves should be worn during the preparation and insertion of the LMA™ *airway to minimize contamination of the device.*

Performance test 1: Visual inspection

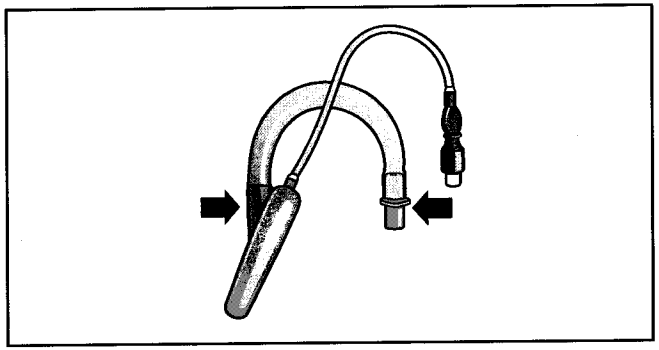
Airway Tube, LMA ProSeal™ Drain Tube, and Connector

- Examine the surface of the LMA™ airway tube and LMA ProSeal™ drain tube for damage, including cuts, tears, or scratches.
- Examine the interior of the airway tube and LMA ProSeal™ drain tube to ensure that they are free from blockages or loose particles. Any particles present in the tubes should be removed.
- Examine the transparency of the tubes. Reusable aiway tubes will gradually discolor with age and re-use.

WARNING: Do not use the LMA™ *airway if the tubes are discolored, as this impairs the ability to see and effectively remove foreign particles during cleaning or to see regurgitated fluids during use.*

WARNING: Do not use the LMA™ *airway if it is damaged or if visible particles cannot be removed from inside the airway tube as they may be inhaled by the patient after insertion.*

- Flex the LMA Classic™ or LMA Unique™ airway tube up to, but not beyond 180°, pressing at the points and in the direction shown by the arrows (Figure 7). Should the tube kink, discard the LMA Classic™ or LMA Unique™ airway.



WARNING: Do not use the LMA Classic™ *or* LMA Unique™ *airway if the airway tube kinks when flexed through 180°, as such an airway may become obstructed during use.*

Fig. 7: Airway tube kink test.

- Examine the 15 mm connector. It should fit tightly into the outer end of the airway tube. Ensure that it cannot easily be pulled off by hand using reasonable force. Do not use excessive force or twist the connector as this may break the seal.

WARNING: Do not use the LMA™ *airway if the mask connector does not fit tightly into the outer end of the airway tube.*

Cuff and Bowl of Mask

- Examine the surface of the cuff for damage, including cuts, tears, and scratches.
- Examine the interior of the mask bowl to ensure it is free from blockages or loose particles. Any particles should be removed.
- Examine the aperture in the LMA Classic™, LMA Flexible™, single use LMA Flexible™, and LMA Unique™. Gently probe the two flexible bars traversing the mask aperture to ensure they are not broken or otherwise damaged. If the aperture bars are not intact, the epiglottis may obstruct the airway.

WARNING: Do not use the LMA™ *airway if the aperture bar is broken or otherwise damaged.*

- Ensure that the section of the LMA ProSeal™ drain tube lying within the bowl of the mask is not torn or perforated, and that there is no contamination between the tube and the mask.
- Examine the rear cuff of the LMA ProSeal™, if present, for wrinkles or folds suggesting herniation.

Performance test 2: Inflation and deflation

- Carefully insert a syringe into the valve port and fully deflate the device so that the cuff walls are tightly flattened against each other. To deflate the LMA ProSeal™, make sure the red manual vent is closed. Remove the syringe from the valve port. Examine the cuff walls to determine whether they remain tightly flattened against each other.

WARNING: Do not use the LMA™ *airway if the cuff walls reinflate immediately and spontaneously, even if only slightly.*

- Examine the fully deflated LMA ProSeal™ mask for wrinkles or folds suggesting herniation. If obvious wrinkles are apparent, the rear cuff may be severely herniated and the LMA ProSeal™ should not be used.

- Inflate the cuff with 50% more air than the recommended maximum clinical inflation volume (see Table 3). Any tendency of the cuff to deflate indicates the presence of a leak and should be evident within two minutes. Examine the symmetry of the inflated cuff. There should be no uneven bulging at either end or sides.

Table 3: Test Cuff Over-Inflation Volumes

LMA™ AIRWAY	AIR VOLUME*
Size 1	6 mL
Size 1 1/2	10 mL
Size 2	15 mL
Size 2 1/2	21 mL
Size 3	30 mL
Size 4	45 mL
Size 5	60 mL
Size 6	75 mL

**Inflate the cuff with these volumes for testing only.*
See Table 4 in back of manual for maximum cuff inflation volumes for patient use.

WARNING: Do not use the LMA™ *airway if cuff leakage is present or if there is uneven bulging of the cuff.*

- While the device remains 50% over-inflated, examine the inflation balloon. The balloon shape should be a thin, slightly flattened elliptical shape, not spherical.

WARNING: Do not use the LMA™ *airway if the inflation balloon is spherical or irregularly shaped as it may be difficult to gauge the pressure of the cuff.*

- While the device remains 50% over-inflated, inspect the interior of the LMA ProSeal™ drain tube from both ends of the mask. Ensure that the tube is not collapsed or perforated.

WARNING: Use of an LMA ProSeal™ *with a collapsed or occluded drain tube may prevent venting of the stomach or insertion of a gastric tube and may permit inflation of the stomach and possible regurgitation. Use of a perforated or torn drain tube may prevent the* LMA ProSeal™ *from being inflated or allow for escape of anesthetic gases.*

8.1 Pre-insertion preparation

Prior to insertion of any LMA™ airway, the cuff should be tightly deflated so that it forms a smooth wedge shape without any wrinkles. This can be accomplished by compressing the mask tip between finger and thumb to achieve the correct wedge shape (Figure 8a). Alternatively, an LMA™ airway Cuff-Deflator or LMA ProSeal™ Cuff-Deflator (Figure 8b) can be used. While deflating, pull back gently on the inflation line to obtain the correct shape for insertion.

Prior to deflating the LMA ProSeal™ and during clinical use, make sure the red manual vent is closed.

A completely deflated, smooth leading edge facilitates insertion, avoids deflection of the epiglottis, or entry of the tip into the glottis. Optimal deflation facilitates complete insertion of the LMA™ airway and correct positioning of the mask (Figure 9).

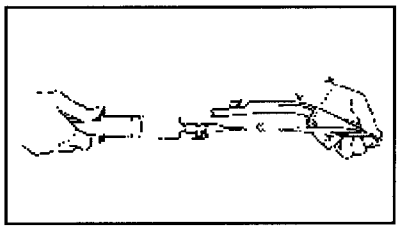


Fig. 8a: LMA™ *airway deflation using manual technique. Note how the inflation line is gently pulled back.*

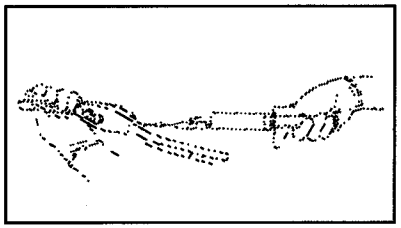


Fig. 8b: LMA ProSeal™ *deflation using* LMA ProSeal™ Cuff-Deflator. *Note how the inflation line is gently pulled back.*

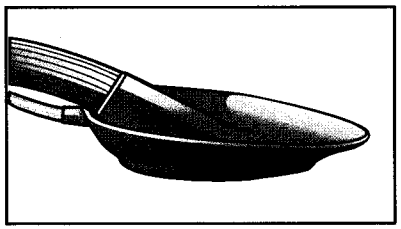


Fig. 9: LMA™ *cuff properly deflated for insertion.*

Lubrication of the posterior surface of the cuff should be performed just before insertion to prevent drying of the lubricant. Apply a bolus of lubricant to the posterior tip of the deflated cuff. It is not necessary to spread the lubricant over the mask surface.

WARNING: Lubricate only the posterior surface of the cuff to avoid blockage of the airway aperture or aspiration of the lubricant.

A water-soluble lubricant, such as K-Y Jelly®, should be used. Do not use silicone-based lubricants as they degrade the silicone components. Lubricants containing lidocaine are not recommended for use as it may delay the return of protective reflexes, provoke an allergic reaction, or affect surrounding structures, including the vocal cords.

8.2 Introduction

Before using any LMA™ airway, the user should be familiar with the instructions contained in this manual. If the device is inserted incorrectly, an unreliable or obstructed airway may be obtained. In addition, an incorrectly placed mask may result in failure of the LMA ProSeal™ drain tube to channel fluids or gases from the stomach and may increase the likelihood of gastric insufflation if used with PPV. Always check for proper placement after insertion (see Sections 8.4, 8.5 and 8.8).

WARNING: An incorrectly placed mask may result in an unreliable or obstructed airway or failure of the LMA ProSeal™ *drain tube to channel fluids or gases from the stomach and may increase the likelihood of gastric insufflation if used with PPV. Always check for proper placement after insertion.*

Before insertion it is important to note the following points:

- Check that the size of the device is appropriate for the patient (see Table 4 in back of manual).The ranges are approximate and clinical judgment should be used in selecting an appropriate size.
- The cuff must always be fully deflated by firmly pulling back on the deflating syringe and gently pulling on the inflation line.
- Check the shape of the cuff and its lubrication, as described previously.
- Have a spare sterile LMA™ airway ready and prepared for immediate use. Where possible, an alternative size of LMA™ airway should also be available.
- Pre-oxygenate and implement standard monitoring procedures.
- Achieve an adequate level of anesthesia before attempting insertion. Resistance or swallowing indicates inadequate anesthesia. Retching indicates inadequate anesthesia and/or inappropriate technique. Inexperienced users should choose a deeper level of anesthesia.
- The ideal head position is extension of the head with flexion of the neck in the position normally used for tracheal intubation ("the sniffing position").This can be achieved by pushing the head from behind with the non-dominant hand during the movement of insertion. A pillow can also be used to keep the neck flexed.
- Excessive force must be avoided at all times.
- When using the LMA ProSeal™ Introducer, it may be possible to reduce or eliminate head and neck manipulation.
- Make sure the LMA ProSeal™ red manual vent is closed during clinical use.

WARNING: Make sure the LMA ProSeal™ *red manual vent is closed during clinical use to prevent deflation of the cuff.*

8.3 Insertion methods

The LMA Classic™, LMA ProSeal™, LMA Flexible™, single use LMA Flexible™, and LMA Unique™ may be inserted using the standard index finger or the thumb technique, depending on access to the patient.

The LMA ProSeal™ may also be inserted using the LMA ProSeal™ Introducer. The dedicated Introducer may provide a more useful method of insertion than the thumb/finger techniques, when using LMA ProSeal™ sizes 1-2 1/2.

All three techniques follow the same principles. To position the LMA™ airway correctly, the cuff tip must avoid entering the valleculae or the glottic opening and must not become caught up against the epiglottis or the arytenoids. The cuff must be deflated in the correct wedge shape (Figure 9) and should be kept pressed against the patient's posterior pharyngeal wall. To avoid contact with anterior structures during insertion, the inserting finger must press the tube upwards (cranially) throughout the insertion maneuver.

Index finger insertion technique

Hold the LMA™ airway like a pen, with the index finger placed at the junction of the cuff and the airway tube. When using the LMA ProSeal™, the fingertip should be pushed into the Introducer strap (Figures 10a and 10b).

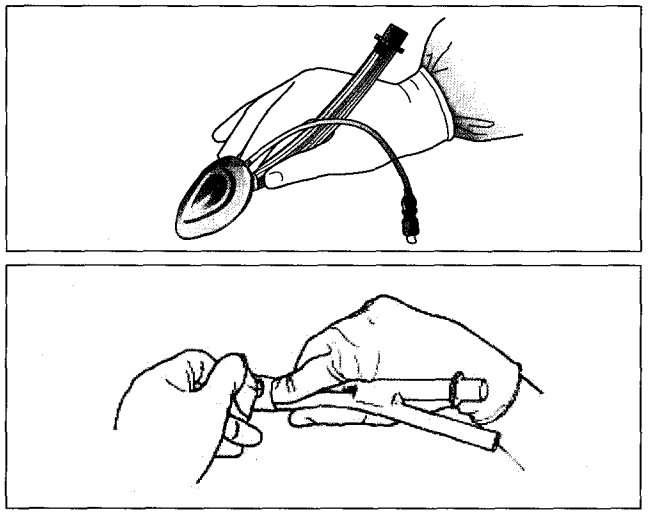
Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it. Note the position of the hand and wrist (Figure 11). A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff is correctly flattened against the palate before proceeding. Further opening of the mouth makes it easier to verify the position of the mask. Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.

As the index finger passes further into the mouth, the finger joint begins to extend (Figure 12). The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask.

Using the index finger, press backward toward the other hand, which exerts counter-pressure (Figure 13). Do not use excessive force. Advance the device into the hypopharynx until a definite resistance is felt (Figure 14).

Depending on patient size, the finger may be inserted to its fullest extent into the oral cavity before resistance is encountered. Because of the flexible nature of the airway tube, the practice of inserting the index finger to its fullest extent is especially important for successful insertion of the LMA Flexible™ / single use LMA Flexible™. Before removing the finger, the non-dominant hand is brought from behind the patient's head to press down on the airway tube (Figure 15).This prevents the LMA™ airway from being pulled out of place when the finger is removed. It also permits completion of insertion in the event that this has not been achieved by the index finger alone. At this point the LMA™ airway should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.

Figures 10-15: Insertion of the LMA™ Airway using the Index Finger Technique.



Figs. 10a and 10b: Hold the LMA™ *airway with the index finger at the cuff/tube junction or in the* LMA ProSeal™ *Introducer strap.*

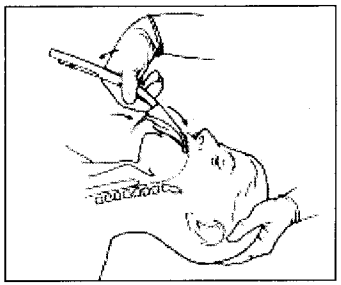


Fig. 11: Press the mask up against the hard palate. Note the flexed wrist

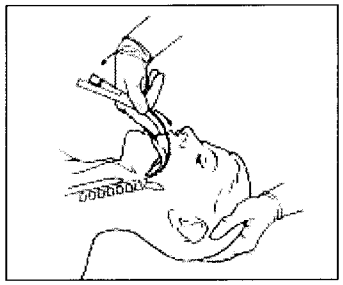


Fig. 12: Slide the mask inward, extending the index finger.

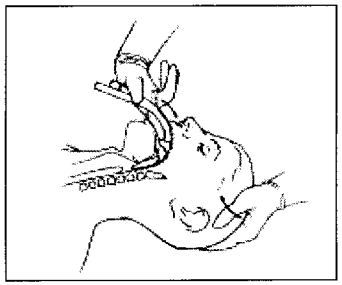


Fig. 13: Press the finger towards the other hand, which exerts counter-pressure.

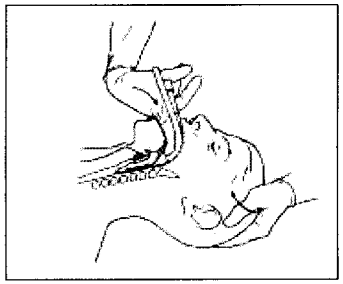


Fig. 14: Advance the LMA™ cuff into the hypopharynx until resistance is felt.

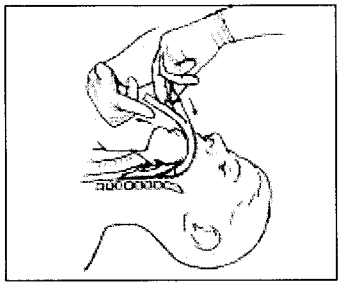


Fig. 15: Hold the outer end of the airway tube while removing the index finger.

Thumb insertion technique

The thumb insertion technique is useful if it is difficult to get access to the patient from behind. The LMA™ airway is held with the thumb in the position occupied by the index finger, i.e., cuff/tube junction or into the strap as shown in Figure 16. Insertion is similar to that using the index finger. As the thumb nears the mouth, the fingers are stretched forward over the patient's face. The thumb is advanced to its fullest extent. The pushing action of the thumb against the hard palate also serves to press the head into extension (Figures 17-20).

Figures: 16-20: Insertion of the LMA™ Airway using the Thumb Technique.

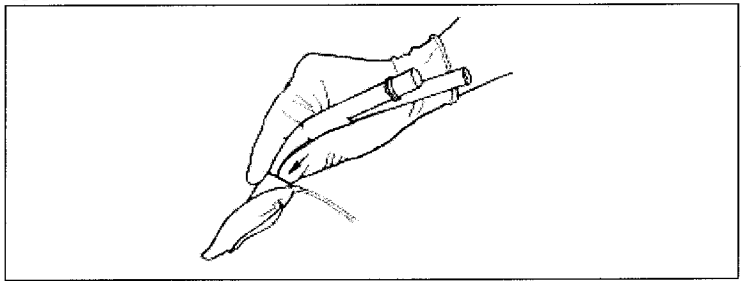


Fig. 16: Hold the LMA™ *airway with the thumb at the cuff/tube junction or, in the case of the* LMA ProSeal™*, with the thumb in the strap.*

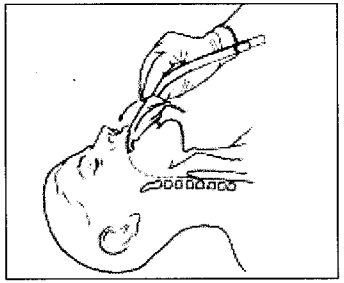


Fig. 17: Place the mask against the palate.

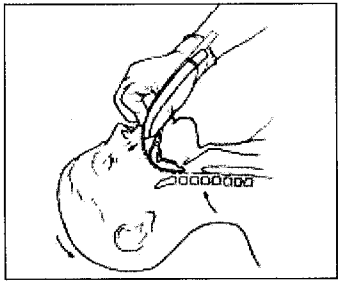


Fig. 18: When the thumb is against the palate, press upward to extend head.

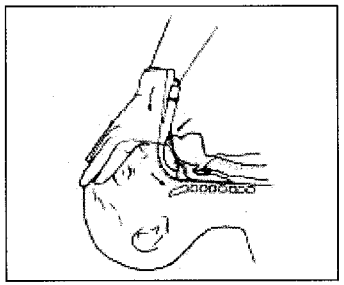


Fig. 19: Extend fingers over head, allowing the thumb to pass inward.

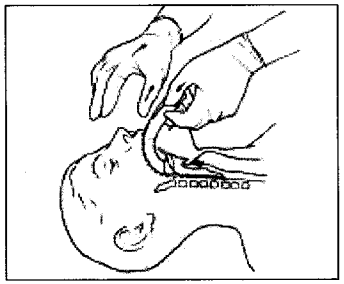


Fig. 20: Use other hand to complete insertion as shown.

Introducer technique (LMA ProSeal™ only)

Choose the correct size of Introducer as shown in Table 5 in the back of the manual. Place the tip of the Introducer into the strap at the rear of the cuff (Figure 21a). Fold the tubes around the convex surface of the blade and fit the proximal end of the airway tube into the matching slot in the tool (Figure 21b). The LMA ProSeal™ is shown mounted in the Introducer in Figure 22.

Under direct vision, press the tip of the cuff upward against the hard palate and flatten the cuff against it (Figure 23). During insertion, the back of the mask should be in contact with the hard palate and the bowl of the mask should be facing the tongue. Verify the position of the mask and slide the cuff further inward against the palate (Figure 24). Push the jaw downward with your middle finger or instruct an assistant to pull the lower jaw downward momentarily.

A high arched palate may require a slightly lateral approach. Look carefully into the mouth to verify that the tip of the cuff has not folded over.

Keeping the Introducer blade close to the chin, rotate the device inward in one smooth circular movement (Figure 25). During insertion, follow the curve of the rigid insertion device. The jaw should not be held widely open during this movement as this may allow the tongue and epiglottis to drop downward, blocking passage of the mask. Do not use the handle as a lever to force the mouth open. Advance into the hypopharynx until a definite resistance is felt (Figure 26).

Before removing the insertion device, the non-dominant hand is brought from behind the patient's head to stabilize the airway tube (Figure 27). This prevents the LMA ProSeal™ from being pulled out of place when the Introducer is removed. It also permits completion of insertion in the event that full insertion has not been achieved by the Introducer alone. At this point the LMA ProSeal™ should be correctly located with its tip firmly pressed up against the upper esophageal sphincter.

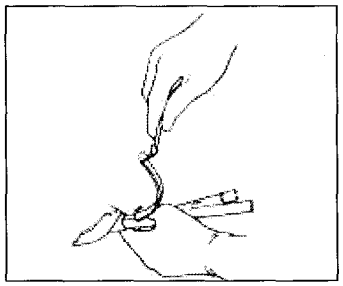


Fig. 21a: Place tip of the Introducer into the strap.

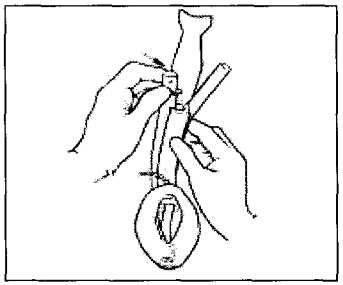


Fig. 21b: Fold the tubes around the Introducer and fit the proximal end of the airway tube in the matching slot.

Figures 22-27: Insertion of the LMA ProSeal™ using the Introducer.

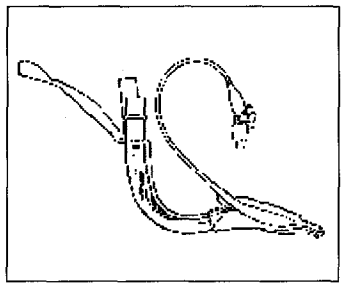


Fig. 22: LMA ProSeal™ with the Introducer in place.

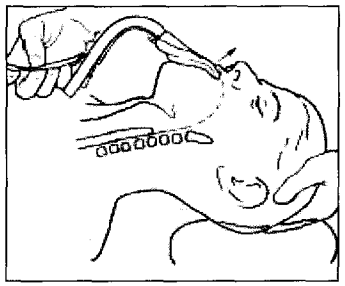


Fig. 23: Press the tip of the cuff against the hard palate.

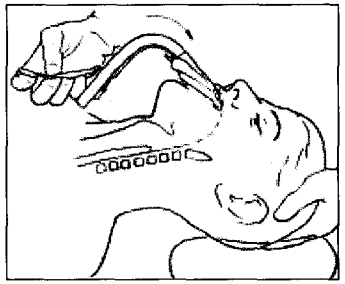


Fig. 24: Press the cuff further into the mouth maintaining pressure against the palate.

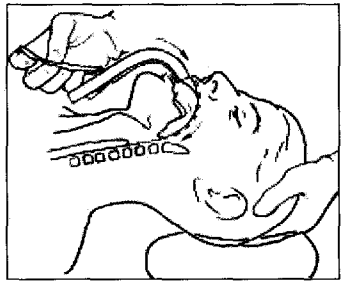


Fig. 25: Swing the device inward with a circular motion, pressing against the contours of the hard and soft palate.

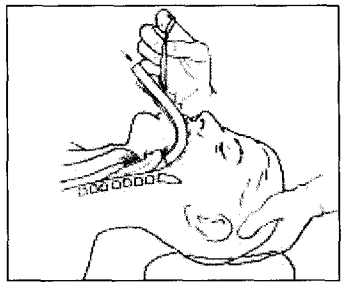


Fig. 26: Advance the LMA ProSeal™ into the hypopharynx until resistance is felt.

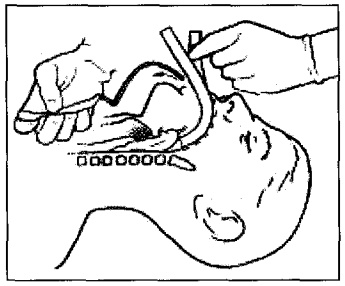


Fig. 27: Hold the tube in place while removing the Introducer.

8.4 Insertion problems

An inadequate depth of anesthesia may result in coughing and breathholding during insertion. If this occurs, anesthesia should be deepened immediately with inhalational or intravenous agents and manual ventilation instituted.

If the patient's mouth cannot be opened sufficiently to insert the mask, first ensure that the patient is adequately anesthetized. An assistant can be asked to pull the jaw downward. This maneuver makes it easier to see into the mouth and verify the position of the mask. However, do not maintain downward jaw traction once the mask has passed beyond the teeth.

The inserting finger must press the tube against the palate throughout the insertion maneuver, otherwise the tip may fold on itself or impact on an irregularity or swelling in the posterior pharynx (e.g., hypertrophied tonsils). If the cuff fails to flatten or begins to curl over as it is advanced, it is necessary to withdraw the mask and reinsert it. In case of tonsillar obstruction, a diagonal shift of the mask is often successful.

If difficulty persists with the chosen technique, one of the other techniques described above should be used.

WARNING: *To avoid trauma, force should not be used at any time during insertion of an* LMA™ *airway.*

8.5 Inflation

After insertion, the tubes should emerge from the mouth directed caudally. Without holding the tubes, inflate the cuff with just enough air to achieve an intracuff pressure of 60 cm H_2O (Figure 28). Note: The inflation amounts printed in Table 4 in the back of the manual and directly onto the airway tube are the MAXIMUM clinical inflation volumes and should not automatically be considered the recommended inflation volumes. Frequently, only half the maximum volumes are sufficient to obtain a seal and/or achieve 60 cm H_2O intracuff pressure. Never overinflate the cuff. Avoid intracuff pressures greater than 60 cm H_2O.

WARNING: *Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.*

The initial cuff volume will vary according to the patient, size of device, head position, and anesthetic depth. During cuff inflation, do not hold the tube as this prevents the mask from settling into its correct location. A small outward movement of the tube is sometimes noted as the device seats itself in the hypopharynx. The signs of correct placement may include one or more of the following: the slight outward movement of the tube upon inflation, the presence of a smooth oval swelling in the neck around the thyroid and cricoid area, or no cuff visible in the oral cavity.

WARNING: *Never over-inflate the cuff after insertion.*

8.6 Connecting to the anesthetic system

Taking care to avoid dislodgment, connect to the anesthetic circuit and employ gentle manual ventilation to inflate the lungs, noting whether there are any leaks. Auscultation and capnography should be used to confirm adequate gas exchange. Auscultate in the anterolateral neck region to check for abnormal sounds that might indicate mild laryngeal spasm or light anesthesia.

8.7 Fixation

The LMA ProSeal™ has a built-in bite-block. For the other LMA™ airways, a bite-block must be inserted before taping the device in place. The bite-block can be fabricated from three or four 4 x 4 gauze pads tightly rolled and taped into a cylindrical pad. Do not use an oral Guedel airway as a bite-block. The gauze bite-block should be at least 3 cm thick for adults and at least 2 cm thick for children. This is twisted in place alongside the airway tube. The device should be then fixed in place using adhesive tape as shown in Figure 29. Apply gentle pressure to the outer end of the airway tube as it is fixed. This ensures that the tip of the mask is pressed securely against the upper esophageal sphincter. The use of the bite block and correct taping procedures stabilizes the LMA™ airway and prevents potential occlusion of the tube. Keep the bite-block in place until the LMA™ airway is removed.

WARNING: *Use of a bite-block reduces the possibility of the danger of airway obstruction or tube damage. A bite-block should be used with all* LMA™ *airways and kept in place until* LMA™ *airway removal.*

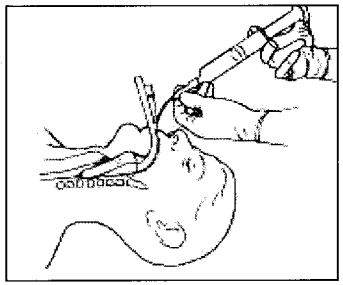


Fig. 28: Inflate the LMA™ *cuff, do not exceed 60 cm* H_2O *pressure.*

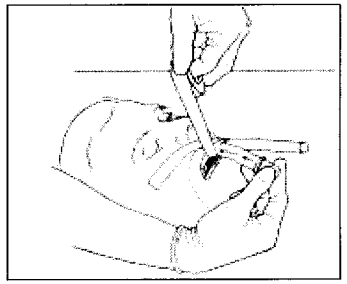


Fig. 29: Fix the LMA™ *airway in place using adhesive tape.*

8.8 Diagnosis of correct and incorrect LMA ProSeal™ position

When inserting and inflating the LMA ProSeal™, look carefully at the front of the neck to observe whether the cricoid cartilage moves forward, indicating correct passage of the mask tip behind it. Correct placement (Figure 30a) should produce a leak-free seal against the glottis with the mask tip wedged against the upper esophageal sphincter. The bite-block should lie between the teeth. If the mask lies too proximal as the result of incomplete insertion, gas will leak from the proximal end of the drain tube when the lungs are inflated (Figure 30b). This situation must be corrected by repositioning the mask. Do not attempt to overcome the leak by occluding the drain tube.

The LMA ProSeal™ drain tube provides additional means to diagnose correct placement. To facilitate diagnosis of correct mask placement, place a small bolus (1-2 ml) of lubricant gel in the proximal end of the drain tube. In a properly placed mask, there should be a slight up-down meniscus movement of the lubricant. If there is no movement or the bolus of lubricant is ejected, the mask may be incorrectly placed.

Occasionally a poorly deflated or inserted mask may enter the vestibule of the larynx (Figure 30c). In this situation, there may be some obstruction to ventilation and gas may leak from the proximal end of the drain tube. In spite of adequate anesthesia, obstruction worsens if the mask is pressed in further. The mask should be removed and reinserted.

Poor insertion or deflation may also cause the tip of the mask to fold back on itself in the hypopharynx, causing the drain tube to become obstructed (Figure 30d). If the tip is folded

back there may be a lack of meniscus movement in the lubricant gel. A simple, noninvasive method to test for this problem would be to pass a gastric tube down to the end of the mask tip to verify that the drainage tube is patent. If the gastric tube cannot reach the distal end of the drain tube, the mask tip is likely folded over. Alternatively, this may be confirmed with a fiberoptic scope. The mask should be removed and reinserted.

To distinguish between the mask lying too high (Figure 30b) and having entered the glottis (Figure 30c), press the mask further inwards. This overcomes a leak if the mask is too high, but causes increased obstruction to ventilation if the mask tip has entered the glottis. If leaks occur from the drain tube even though the device is correctly positioned, this may indicate a damaged device (e.g., a torn or perforated internal drain tube). If the device is damaged in any way, it should not be used.

WARNING: *An incorrectly placed* LMA ProSeal™ *may result in obstruction to ventilation or failure of the drain tube to channel fluids or gases from the stomach and may increase the likelihood of gastric insufflation if used with PPV. Always check for proper placement after insertion.*

A guide for facilitating correct LMA ProSeal™ position is included in the Appendix.

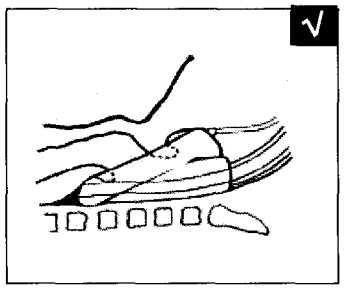


Fig. 30a: Correct placement. Good seals at glottis and upper esophageal sphincter.

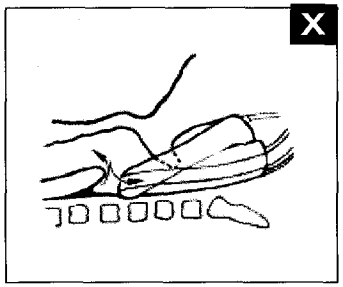


Fig. 30b: Incorrect placement. LMA ProSeal™ *placed too high in pharynx, poor seal allowing gas and fluid to pass in directions shown by arrows; can be eliminated by pressing the mask in further.*

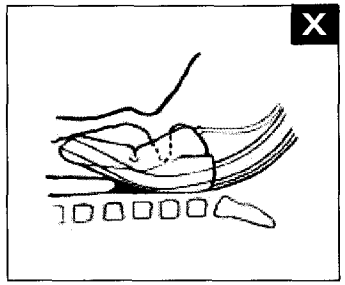


Fig. 30c: Incorrect placement. LMA ProSeal™ *incorrectly placed with tip in laryngeal vestibule; ventilation is obstructed and deteriorates if mask is pressed in further.*

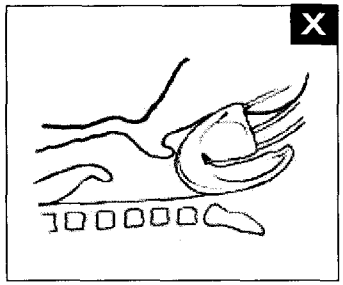


Fig. 30d: Incorrect placement. LMA ProSeal™ *mask folded back on itself in the hypopharynx, causing the drain tube to become obstructed.*

As with other methods of airway management, the use of pulse oximetry and capnography is recommended when using the LMA™ airway. The LMA™ airway may be used for either spontaneous or controlled ventilation.

9.1 Spontaneous ventilation

The LMA™ airway is well tolerated in spontaneously breathing patients when used with volatile agents or intravenous anesthesia provided anesthesia is adequate to match the level of surgical stimulus and the cuff is not overinflated.

Coughing, breathholding, or movement may result if the induction agent is allowed to wear off before adequate levels of anesthesia for maintenance have been obtained. This is particularly likely to occur following the introduction of an external stimulus such as surgery or turning the patient when the level of anesthesia has been misjudged. Ventilation should be assisted gently until breathing returns.

9.2 Positive pressure ventilation (PPV)

All LMA™ airways may be used with PPV; however, the LMA ProSeal™ has been specifically designed for use with PPV, with and without muscle relaxants. The softer cuff material, deeper mask bowl, and special cuff shape of the LMA ProSeal™ permit a more effective seal against the laryngeal inlet at lower mucosal pressures when compared to the LMA Classic™.[4]

When a relaxant technique is chosen, the relaxant drug may be given either before or after insertion. Alternatively, if a change in the surgical or diagnostic procedure requires conversion to a relaxant technique, a muscle relaxant can be given at any time.

The following points should be observed when using the LMA™ airway with PPV:

- Tidal volumes should not exceed 8 ml/kg, and peak inspiratory pressures should be kept within the maximum airway seal pressure, which will be found to vary between individual patients, but is, on average, up to 20 cm H_2O with the LMA Classic™, LMA Flexible™, single use LMA Flexible™, and LMA Unique™ and up to 30 cm H_2O with the LMA ProSeal™.
- If leaks occur during PPV, this may be due to:
  - Light anesthesia causing a degree of glottic closure,
  - Inadequate neuromuscular blockade,
  - Reduction in lung compliance related to the procedure or patient factors, or
  - Displacement or migration of the cuff by head turning or traction.
- Should air leakage through the LMA ProSeal™ drain tube be observed during PPV, even though anesthesia is adequate, this may be due to the mask having migrated proximally. Ensure the securing tape is still in place and readjust as necessary while pressing the tubes downward to relocate the mask tip against the upper esophageal sphincter.

In the event of a leak around the cuff, do not simply add more air to the cuff. This will not necessarily improve the seal pressure and may make the leak worse by adding tension to the normally soft cuff, pushing it away from the larynx.

9.3 Potential problems after insertion

Inadequate level of anesthesia

The most common problem following insertion is failure to maintain an adequate level of anesthesia. Administer an additional bolus of induction agent and/or increase the concentration of volatile agent, while gently assisting ventilation.

Nitrous oxide diffusion

Nitrous oxide diffuses into the silicone cuff causing a rise in intracuff pressure. Studies have shown that use of nitrous oxide can increase reusable LMA™ airway cuff pressure by as much as 1 mm Hg per minute. The LMA Unique™ and single use LMA Flexible™ PVC cuffs are much more resistant to nitrous oxide diffusion.

Diffusion rate and resulting peak pressure may vary with the initial volume of air injected into the cuff, the type of gases used to inflate the cuff, the percentage of nitrous oxide in the inhaled mixture, and the size of the device.

The incidence of post-operative sore throat may increase if intracuff pressure becomes excessive. To reduce the risk of a sore throat or possible neurovascular injury, the cuff pressure should be periodically checked and gas intermittently withdrawn to maintain 60 cm H_2O intracuff pressure or the minimal "just seal" pressure.

This can be achieved in several different ways. First, a pressure monitor or pressure transducer may be used. Pressure manometers are commercially available from Posey, Mallinckrodt, Portex, and VBM-Medical. Secondly, simply feeling the inflation indicator balloon can be performed. At intracuff pressure of 60 cm H_2O, the inflation balloon should feel very compliant. If the inflation indicator balloon becomes stiff or olive-shaped, this indicates excessive pressure. Finally, gas can be withdrawn until there is a slight leak, and then 1-2 ml added.

WARNING: Excessive intracuff pressure can result in malposition and pharyngolaryngeal morbidity, including sore throat, dysphagia and nerve injury.

Poor airway seal/Air leak

Should signs of a poor airway seal or air leak occur at the beginning or during a case, one or more of the following measures may be taken:

- Verify the depth of anesthesia is adequate and deepen if necessary.
- Check cuff pressures at start and periodically during a case, especially if using nitrous oxide.
- Ensure intracuff pressures are not >60 cm H_2O; reduce intracuff pressure, if necessary, while maintaining an adequate seal.
- If the mask is seated too high in the pharynx, then press in further to confirm contact with the upper esophageal sphincter.
- Ensure proper fixation by applying palatal pressure while taping in place.
- Always confirm cuff integrity prior to placement.

Malposition of the LMA™ airway

In general, malposition of the LMA™ airway can be assessed by capnography or by observation of changes in tidal volume, e.g., a reduced expired tidal volume. If malposition is suspected, check whether there is a smooth, oval neck swelling extending below the thyroid cartilage. If absent, it may indicate anterior misplacement of the mask tip into the laryngeal inlet, particularly if there is an unusually prolonged expiratory phase. If malposition is suspected, the LMA™ airway may be removed and reinserted once anesthetic depth is adequate for reinsertion.

Specific malpositions of the LMA ProSeal™ were discussed in Section 8.8. In addition, migration/rotation of the LMA ProSeal™ during use may occur due to overinflation of the cuff, a herniated cuff and/or accidental displacement. Check cuff pressure at the start and periodically during a case, verify cuff integrity prior to use and ensure proper fixation. If the LMA ProSeal™ pops out of the mouth during insertion, the mask may be incorrectly positioned with the distal tip folded backward in the pharynx. Remove and reinsert or digitally sweep behind the tip.

Unexpected regurgitation

Even in fasted patients, regurgitation may occur for a variety of reasons (for example, if anesthesia becomes inadequate), resulting in fluid emerging from the LMA™ airway tube or the LMA ProSeal™ drain tube. It has been shown in cadavers that fluids pass up the LMA ProSeal™ drain tube without laryngeal contamination when the mask has been correctly placed.[9]

If regurgitation occurs, provided that oxygen saturation remains at acceptable levels, the LMA™ airway should not be removed. The patient should immediately be tilted head down. Momentarily disconnect the anesthetic circuit so that gastric contents are not forced into the lungs. Verify that anesthetic depth is adequate and deepen anesthesia intravenously, if appropriate. Reposition the device to ensure the distal end is lying against the upper esophageal sphincter and secure it in place using the fixation method described earlier.

Suction should then be applied through the airway tube. Suction of the tracheobronchial tree using a fiberoptic bronchoscope through the airway tube may be employed if the airway reflexes are adequately obtunded.

If clinically indicated, commence preparation for immediate tracheal intubation of the patient. If aspiration has occurred, the patient should receive a chest X-ray and be treated, as clinically appropriate, with antibiotics, physiotherapy, and tracheal suction.

A gastric tube may be inserted behind the LMA™ airway or through the LMA ProSeal™ drain tube to complete drainage if the presence of further gastric contents is suspected.

Airway obstruction with the LMA ProSeal™

There have been reports of airway obstruction occurring with the LMA ProSeal™ airway.[10,11,12] Some of the reports were associated with noisy respiration and negative pressure, causing air to be drawn into the esophagus with inspiration. Other clinicians have reported an increased incidence of stridor with the LMA ProSeal™ airway. One proposed mechanism of the airway obstruction is pressure from the distal mask causing narrowing of the glottic inlet and subsequent mechanical closure of the vocal cords. Another mechanism is folding of the cuff wall medially, causing a physical airway obstruction.

Should the patient show signs of airway obstruction, one or more of the following measures may be taken:

- Verify the depth of anesthesia is adequate and deepen if necessary.
- Ensure intracuff pressures are not >60 cm H_2O; reduce intracuff pressure, if necessary, while maintaining an adequate seal.
- If the patient is spontaneously breathing, provide expiratory PEEP up to a clinically safe level or use PPV.
- Try placing the patient's head and neck in a sniffing position.

- Consider fiberoptic examination to evaluate cuff position and vocal cord function.
- If all else fails, remove and reinsert.
- If appropriate, consider insertion of a smaller sized LMA ProSeal™ airway.

WARNING: If airway problems persist or ventilation is inadequate, the LMA™ *airway should be removed and an airway established by some other means.*

9.4 Emergence from anesthesia and removal

If applicable, reverse the neuromuscular block or allow the block to wear off before switching off the anesthetic agents at the end of the surgical or diagnostic procedure. With gentle assisted ventilation, the patient should be allowed to start breathing spontaneously. At this stage it is advisable to check the intracuff pressure.

The correctly placed LMA™ airway is well tolerated until the return of protective reflexes, provided that intracuff pressures are kept around 60 cm H_2O.This means that a clear airway can be maintained until the patient is able to swallow and cough effectively. Removal should always be carried out in an area where suction equipment and the space for rapid tracheal intubation are present. The following procedure should be followed:

- Patient monitoring should continue throughout the recovery stage. Oxygen should be continuously administered through the anesthetic circuit or via a T-piece. If suction is required around the oral cavity or down the airway tube, it should be carried out prior to recovery of reflexes.
- Leave the patient undisturbed until reflexes are restored, except to administer oxygen and perform monitoring procedures. It is not advisable to move the patient from the supine to the lateral recumbent position unless there is urgent reason to do so, such as regurgitation or vomiting. If the patient needs to be awakened in the lateral position, the patient must be turned in this position under adequate anesthesia.
- Avoid suctioning the airway tube with the LMA™ airway in place. The inflated cuff protects the larynx from oral secretions and suctioning is not likely to be required. Suctioning and physical stimulation may provoke laryngeal spasm if anesthesia is light.
- Watch for signs of swallowing. It is usually safe and convenient to remove adhesive tape when swallowing begins. However, the interval between the beginning of swallowing and the ability to open the mouth varies from patient to patient according to the length and type of anesthesia.
- Deflate the cuff and simultaneously remove the device only when the patient can open the mouth on command. If the cuff is deflated before the return of effective swallowing and cough reflexes, secretions in the upper pharynx may enter the larynx, provoking coughing or laryngeal spasm. Verify airway patency and respiratory depth. Oral suctioning may now be performed, if required.

If the LMA™ airway is to be removed in a Post-Anesthesia Care Unit (PACU), recovery room staff should receive training in all aspects of LMA™ airway management. An anesthesiologist should always be readily available if the device is to be removed away from the operating room.

10.1 Pediatric use

The smaller LMA™ airway sizes have been shown to function effectively in children despite the differences between the adult and the infant larynx. It is recommended that LMA™ airway use in neonates and small children be performed by anesthesiologists familiar with pediatric patients and already experienced in adult LMA™ airway anesthesia.

Table 4 provides basic guidelines for sizing. In children at the transition weights, substitution of one size for another may be necessary.

LMA™ airway insertion in children is carried out in the same way as described for adults following either intravenous or gaseous induction, provided an adequate depth of anesthesia is achieved. Insertion should be successful at the same plane of anesthesia that would be suitable for tracheal intubation. The incidence of airway problems in children with the LMA™ airway seems to follow the same trend as in adults. However, as with any form of anesthesia and airway management in infants and children where ventilation is inadequate, desaturation is likely to occur faster due to their higher oxygen consumption.[13]

LMA™ airway anesthesia in children and infants is associated with maintenance of higher oxygen saturation compared to a face mask and Guedel airway[14] and the ability to cough and cry while waking up. The LMA™ airway is suitable for many short pediatric ambulatory surgical or diagnostic procedures and those where access to the head and neck would otherwise be limited by the use of a face mask.[14]

10.2 Gastric drainage with the LMA™ airway

WARNING: Should the LMA™ *airway be used in a fasted patient who is at risk of retained gastric contents, prophylactic measures to empty the stomach contents and appropriate antacid therapy should be employed. Examples of conditions where fasted patients may be at risk of retained gastric contents include, but are not limited to: hiatal hernia and moderate obesity.*

10.2.1 LMA Classic™, LMA Unique™, LMA Flexible™ and single use LMA Flexible™

Gastric drainage through a gastric tube is compatible with the LMA™ airway and does not interfere with its seal against the larynx. The gastric tube is best passed before LMA™ airway insertion, but it is possible to pass it during anesthesia, if necessary, by slight deflation of the LMA™ airway cuff. A Magill's forceps may be used to push the tip down behind the mask. The insertion of a gastric tube does not guarantee that the stomach can be drained completely.

WARNING: The presence of a gastric tube does not rule out regurgitation and may even make regurgitation more likely because the tube may make the lower esophageal sphincter incompetent.

10.2.2 LMA ProSeal™

In addition to its diagnostic function (see Section 8.8), the LMA ProSeal™ drain tube facilitates channeling of fluids and gases out of the patient and/or the insertion of standard gastric (nasogastric or orogastric) tubes into the stomach at any time during the anesthetic procedure (Figure 31). Refer to Table 5 in the back of the manual for maximum gastric tube sizes.

WARNING: Do not attempt to pass a gastric tube through the drain tube in the presence of known or suspected esophageal damage.

If it is clinically indicated to pass a gastric tube into the stomach, suction should not be performed until the gastric tube has reached the stomach. Suction should not be applied directly to the end of the drain tube, as this may cause the drain tube to collapse and cause possible injury to the upper esophageal sphincter.

WARNING: To prevent injury to the upper esophageal sphincter, do not apply suction directly to the end of the drain tube.

The gastric tube should be well lubricated and passed slowly and carefully. When such tubes are used in conjunction with the LMA ProSeal™, it is important to avoid the potential for trauma associated with excessive tube rigidity. For this reason, do not use gastric tubes which have been stiffened by refrigeration. Ensure the tube is at or above room temperature. Some resistance is often detected as the tip of the gastric tube is pressed gently against the upper esophageal sphincter. Force must never be used. If a tube of appropriate size fails to pass (Table 5), the mask may be kinked or malpositioned. In these cases the mask should be removed and reinserted. Do not try to force the tube through (Figure 32).

WARNING: To avoid trauma, force should not be used at any time during insertion of a gastric tube through the LMA ProSeal™ *drain tube.*

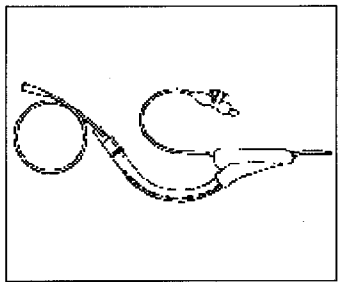


Fig. 31: LMA ProSeal™ *with gastric tube.*

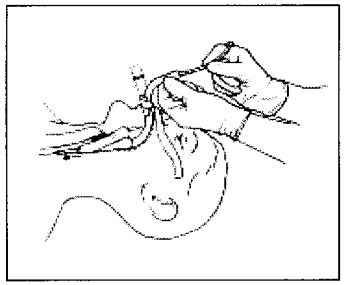


Fig. 32: Passage of gastric tube through LMA ProSeal™ *and through upper esophageal sphincter.*

10.3 Use of the LMA Flexible™ / single use LMA Flexible™

If surgical procedures are being done in close proximity to the LMA Flexible™ / single use LMA Flexible™, the surgeon should be very careful to avoid displacing or damaging the mask.

10.3.1 Ventilation with LMA Flexible™

The airway tube of the LMA Flexible™ / single use LMA Flexible™ is of smaller internal diameter and longer length than that of the other LMA™ airways. This facilitates surgical access but the anesthesiologist should be aware of the greater flow resistance offered by the smaller diameter tube.

10.3.2 Use of throat pack with LMA Flexible™ / single use LMA Flexible™

The correctly placed LMA™ cuff acts as a barrier, preventing soiling of the glottis or trachea by blood or secretions from above, making it possible to use the LMA™ airway for surgical procedures in the pharynx and nasal/sinus cavities.[15,16,17] The LMA™ cuff does not, however, protect against pulmonary aspiration in case of vomiting or regurgitation. Where the surgeon is not able to perform pharyngeal suction under direct vision, it may be wise to insert a throat pack after insertion of the LMA Flexible™/ single use LMA Flexible™. If it is decided to insert a throat pack, always inflate the LMA™ cuff first with the recommended volume of air (enough air to obtain a seal/60 cm H_2O). When inserting the throat pack, the surgeon should take care to avoid displacing the mask. Check airway patency before and after pack insertion. If there is any doubt about airway patency, remove the pack and reposition the mask.

10.4 Use with magnetic resonance imaging (MRI)

Testing has been performed to determine LMA™ airway compatibility with MRI. Prior to using an LMA™ airway in this environment, the user should carefully compare the equipment and test conditions described with those planned for use in the actual clinical environment. Refer to the Appendix for detailed results of device testing in the MRI environment.

10.5 Use with endoscopy and fiberoptic intubation

Since the distal end of the airway tube faces the opening of the larynx, the LMA™ airway can be used as a guide to fiberoptic visualization of the larynx and trachea while ventilation is maintained.

Table 1 in the back of the manual shows the internal diameters and tube lengths of the different LMA™ airways. The airway tube of the LMA ProSeal™ is of slightly smaller diameter than the LMA Classic™, but is of larger diameter than the LMA Flexible™ / single use LMA Flexible™. Consequently, smaller diameter bronchoscopes should be used with the LMA ProSeal™, LMA Flexible™, and single use LMA Flexible™ than are recommended for the LMA Classic™.

Table 6 shows the maximum fiberoptic bronchoscope and endotracheal tube sizes that can fit through the LMA™ airways. The flexible airway tube of the LMA Flexible™ and single use LMA Flexible™ is too long and of too small diameter to allow passage of an endotracheal tube. However, an endotracheal tube may be guided into place after the device has been removed over a tube changer.

CAUTION: The need for instrumentation should be carefully considered and evaluated prior to insertion of an LMA Flexible™ / *single use* LMA Flexible™. *If the need for instruments that cannot be passed through the device is anticipated, the use of another* LMA™ *airway or an alternate method of airway management should be considered.*

Endoscopy procedure

1. Orient the fiberoptic bronchoscope (FOB) so the tip flexes in the anteroposterior direction.
2. Pass the FOB tip through the airway tube.
3. The epiglottis will usually be observed lying against the aperture bars or against the LMA ProSeal™ drain tube. If the epiglottis is deflected downwards, manipulate the tip of the FOB under the epiglottis until the vocal cords come into view.

Fiberoptic Intubation

4. If intubation through the LMA™ airway is planned, a well-lubricated, fully deflated endotracheal tube (ETT) can be threaded over the FOB.

Alternatively, an ETT with a resealing adaptor may be inserted through the LMA™ airway until the tip just protrudes through the central aperture slot prior to insertion in the patient.

Table 6 in the back of the manual provides guidance for selecting the appropriate size ETT and FOB for use with each LMA™ airway. The compatibility of the ETT and its adaptor should be tested before insertion, since the outside diameter of endotracheal tubes may vary.

5. Administer oxygen throughout the intubation procedure and monitor the adequacy of ventilation by capnography and pulse oximetry.
6. Once the cords are visualized, pass the tip of the FOB into the trachea.
7. Thread the ETT downwards into the trachea over the FOB.
8. Inflate the ETT cuff and ventilate to check for correct position by auscultation and capnography.
9. Leave the LMA™ airway in place with the cuff slightly deflated.
10. Remove the LMA™ airway when protective reflexes have returned.
11. If a larger ETT is needed, remove the LMA™ airway and ETT over a tube changer and guide a larger ETT into place.

Using a slightly longer endotracheal tube may be helpful in fiberoptic intubation through the LMA™ airway in large patients. The microlaryngeal tracheal tube (Mallinckrodt, St. Louis, MO; Rüsch Inc., Duluth, GA) or nasal RAE® tube (Mallinckrodt) offer increased length, which allows the cuff of the ETT to be positioned below the vocal cords in large patients.

10.6 Blind tracheal intubation through the LMA™ airway

In general, use of the LMA Fastrach™ is recommended when blind intubation is anticipated. The success rate of direct blind intubation through the LMA Classic™ airway is highly variable (20-100%)[5] depending on clinician experience, technique, number of attempts, patient anatomy, and available equipment. There are currently no published data on blind intubation through the LMA ProSeal™. There is one published study of blind intubation by paramedics through the LMA Unique™ in a mannequin. The successful blind intubation rate was 21%.[18]

The ET tube is inserted into the LMA Classic™ or LMA Unique ™ airway tube with a slight rotation to the left so the bevel will not catch on the right hand aperture bar. Flexion of the head may help prevent the tube tip from catching on the walls of the larynx anteriorly. Listening down the tube or using capnography may help guide the ET tube into the trachea. If the ET tube passes into the esophagus, slight manipulation of the ET tube or the LMA™ airway may help align the glottic opening and the LMA™ aperture more accurately.

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Safety information for the use of magnetic resonance imaging (MRI) procedures (i.e., imaging, angiography, functional imaging, spectroscopy, etc.) in patients pertains to shielded MR systems with static magnetic fields of 1.5 Tesla or less, gradient magnetic fields of 20 Tesla/second or less, and a maximum whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 30 minutes of imaging.

WARNING: *The effects of performing MRI procedures using MR systems and conditions above these levels have not been determined.*

The LMA ProSeal™, LMA Flexible™, single use LMA Flexible™, LMA Classic™, and LMA Unique™ have been determined to be MR safe. That is, these device, when placed in a patient undergoing an MRI procedure will not present an additional risk to the patient, but may affect image quality depending on the pulse sequence that is used and the imaging area of interest. Whenever possible, the LMA Classic™ or LMA Unique™ should be used, rather than the LMA ProSeal™, LMA Flexible™, or single use LMA Flexible™, as the LMA Classic™ and LMA Unique™ do not have a wire-reinforced airway tube, and are therefore less prone to the listed potential risks or artifacts.

Magnetic resonance imaging (MRI) procedures must only be performed according to the following guidelines:

Static Magnetic Field: The LMA Classic™ and LMA Unique™ do not exhibit magnetic field interactions. A patient with the LMA ProSeal™, LMA Flexible™, or single use LMA Flexible™ may safely undergo an MRI procedure using a shielded MR system with a static magnetic field of 1.5 Tesla or less.

WARNING: *The* LMA ProSeal™ *and* LMA Flexible™*, and single use* LMA Flexible™ *exhibit magnetic field interactions with respect to translational force and torque during exposure to a shielded 1.5 Tesla MR system (maximum spatial gradient, 450 gauss/cm). However, when the* LMA ProSeal™ *or* LMA Flexible™*, or single use* LMA Flexible™ *is properly positioned and adhesive tape or other similar dressing is used to retain the device in place, there is no additional risk to the patient with regard to movement or dislodgment using a shielded MR system with static magnetic field of 1.5 Tesla or less. Thus, when used with MRI, care should be taken to monitor the patient carefully to assure that correct positioning of the* LMA™ *airway tube is maintained.*

Gradient Magnetic Fields: Pulse sequences (e.g., echo planar imaging technique or other rapid imaging pulse sequence), specialized gradient coils or other techniques or procedures that exceed gradient magnetic fields of 20 Tesla/sec must not be used for MRI procedures in a patient with the LMA ProSeal™, LMA Flexible™ or single use LMA Flexible™. Use of unconventional or non-standard MRI techniques have not been assessed and, therefore, must be avoided.

Radiofrequency (RF) Fields of MR Systems: MRI safety tests conducted using a whole body averaged SAR of 1.1 W/kg for 30 minutes indicated that there was no greater than a 0.5°C temperature increase for the LMA ProSeal™, LMA Flexible™ or single use LMA Flexible™. Therefore, MRI procedures must not exceed exposures to RF fields greater than a whole body averaged specific absorption rate (SAR) of 1.1 W/kg for 30 minutes of imaging in a patient with the LMA ProSeal™, LMA Flexible™ or single use LMA Flexible™

CAUTION: *Artifacts for the* LMA™ *airways have been characterized using a 1.5 Tesla MR system and various pulse sequences. Based on this information, MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the* LMA ProSeal™ *or* LMA Flexible™*, single use* LMA Flexible™ *The valve component located at the end of the inflation line should also be directed away from the area of interest to avoid artifacts.*

MRI Artifacts: MRI artifact size is dependent on the type of pulse sequence used for imaging (e.g., larger for gradient echo pulse sequences and smaller for spin echo and fast spin echo pulse sequences) the direction of the frequency encoding direction (larger if the frequency encoding direction is perpendicular to the device and smaller if it is parallel to the device), and the size of the field of view. Positional errors and artifacts on MR images will be smaller for MR systems with lower static magnetic field strengths using the same imaging parameters. The use of fast spin echo pulse sequences will minimize the amount of artifact associated with the presence of the LMA ProSeal™, LMA Flexible™ or single use LMA Flexible™ compared to the use of other imaging techniques.

Summary of MRI Artifact Information

	LMA ProSeal™				LMA Flexible™ / single use LMA Flexible™			
Signal Void Size (1)	2,811	11,981	14,638	21,841	1,492-1,702	3.631-4,008	2,218-4,365	4,484-6,917
Static Magnetic Field (T)	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Pulse Sequence	T1-SE	T1-SE	GRE	GRE	T1-SE	T1-SE	FMPSPGR	FMPSPGR
TR (msec)	500	500	100	100	300	300	50	50
TE (msec)	20	20	15	15	20	20	2.6	2.6
Flip Angle	N/A	N/A	30°	30°	N/A	N/A	30°	30°
Bandwidth	16 kHz	16 kHz	16 kHz	16 kHz	16 kHz	16 kHz	16 kHz	16 kHz
Field of View	24 cm	24 cm	24 cm	24 cm	24 cm	24 cm	24 cm	24 cm
Matrix Size	256 x 256	256 x 256	256 x 256	256 x 256	256 x 128	256 x 128	256 x 128	256 x 128
Section Thickness	5 mm	5 mm	5 mm	5 mm	10 mm	10 mm	10 mm	10 mm
Maximum Readout Gradient Strength	6.3 mT/m	6.3 mT/m	6.3 mT/m	6.3 mT/m	6.3 mT/m	6.3 mT/m	6.3 mT/m	6.3 mT/m
Orientation of Device to Field	Parallel	Perpendicular	Parallel	Perpendicular	Parallel	Perpendicular	Parallel	Perpendicular
Phantom Filler	Gel	Gel	Gel	Gel	Gel	Gel	Gel	Gel

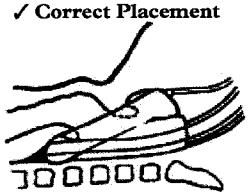
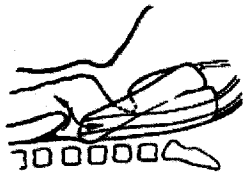
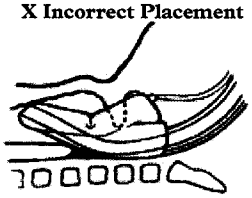
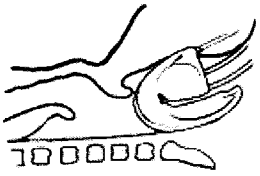
(T1-SE, T1-weighted spin echo; FMPSPGR, fast spoiled gradient recalled echo in the steady state; GRE, gradient echo; N/A, not applicable; values for artifact size indicated in mm²; Note that the T1 and T2 values for the gel used for the phantom filler are similar to the values of skeletal muscle or organ tissue.)

(1) Ranges listed reflect results obtained with largest and smallest size LMA Flexible™ *devices. Values will vary with different sized* LMA Flexible™ *devices*

LMA ProSeal

Steps to facilitate correct mask position.

1. After insertion, inflate the cuff to no more than 60 cm H_2O intracuff pressure.
2. Connect to anesthesia circuit and check for leaks from the drain tube and airway tube.
3. Verify position of bite block.
4. Place a small bolus of lubricant gel on the proximal end of the drain tube and gently squeeze the bag to assess movement.
5. If necessary, pass an orogastric tube to the end of the mask tip to verify the drain tube is patent.
6. Once correctly positioned, apply palatal pressure to tubes while taping in place.

	✓ Correct Placement	X Incorrect Placement	X Incorrect Placement	X Incorrect Placement
				
Mask position	Tip behind arytenoid and cricoid cartilages	Tip too high in pharynx	Tip in laryngeal vestibule	Tip folded backwards
Gas leak from drain tube	No	Yes	Yes	No
Bite block	Approximately midway between teeth	Too high	Approximately midway between teeth	Too high
Lubricant test	Slight meniscus movement	May have movement depending on position	• Marked up/down movement • Ejection of lubricant or spontaneous bubble formation	No meniscus movement
Additional verification	Passing OG tube to mask tip demonstrates drain tube is patent	Pressing in further eliminates leak	Pressing in further increases obstruction	Difficulty passing OG tube indicates occluded drain tube

Tips for troubleshooting problems after LMA ProSeal™ insertion

Problems after Insertion:	Possible Cause(s):	Possible Solution(s):
Poor airway seal/Air leak (audible air leak, poor ventilation)	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Inadequate anesthesia	Deepen anesthesia
	Poor fixation	Ensure palatal pressure and proper fixation
	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O (adjust if necessary)
	Herniation of cuff	Confirm cuff integrity prior to use; deflate entirely prior to autoclaving
Gas leakage up the drain tube with or without PPV	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Open upper esophageal sphincter	Monitor
Airway obstruction (difficult ventilation, phonation, stridor)	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Distal tip of mask pressing on glottic inlet with mechanical closure of vocal cords	Ensure adequate anesthesia and correct cuff inflation pressures Place patient's head/neck in sniffing position Try PPV or add PEEP
	Folding of cuff walls medially	Consider insertion of one size smaller LMA ProSeal™ Ensure correct cuff inflation pressures
Gastric insufflation	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
Migration/Rotation/Mask popping out of mouth	Overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O
	Herniation of cuff	Confirm cuff integrity prior to use
	Accidental displacement	Ensure proper fixation
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Poor fixation	Ensure palatal pressure and proper fixation
Resistance to OG tube insertion	Insufficient lubrication	Add lubricant and re-attempt passing OG tube
	Distal tip of mask folded backward	Remove and reinsert or digitally sweep behind the tip
	Mask seated too high in pharynx	Advance mask in further and re-secure airway tubes with tape
	Incorrect placement in laryngeal vestibule	Remove and reinsert
	Gross overinflation of cuff	Check cuff pressure at start and periodically during case, especially if using nitrous oxide to ensure not > 60 cm H_2O

For questions, please call (800) 788-7999.

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Table 1: Minimum Airway Tube Internal Diameters and Lengths(mm)

LMA™ Airway Size	LMA Classic™ LMA Unique™		LMA ProSeal™		LMA Flexible™		Single use LMA Flexible™	
	ID	Length	ID	Length	ID	Length	ID	Length
1	5.3	115	NA	NA	NA	NA	NA	NA
1 1/2	6.1	135	6.4	135	NA	NA	NA	NA
2	7.0	155	6.4	135	5.1	215	5.1	215
2 1/2	8.4	175	8.0	160	6.1	230	6.1	230
3	10.0	220	9.0	170	7.6	255	7.6	255
4	10.0	220	9.0	170	7.6	255	7.6	255
5	11.5	235	10.0	170	8.7	285	8.7	285
6	*11.5	*235	NA	NA	8.7	285	NA	NA

ID = internal diameter
** Applies to LMA Classic™ only, size 6 not available in LMA Unique™.*

Table 4: LMA™ Airway Selection Guidelines

LMA™ Airway Size	Patient Size	Maximum Cuff Inflation Volumes (air*)
1	Neonates/Infants up to 5 kg	4 mL
1 1/2	Infants 5-10 kg	7 mL
2	Infants/Children 10-20 kg	10 mL
2 1/2	Children 20-30 kg	14 mL
3	Children 30-50 kg	20 mL
4	Adults 50-70 kg	30 mL
5	Adults 70-100 kg	40 mL
6	Adults >100 kg	50 mL

**These are maximum clinical volumes that should never be exceeded. It is recommended the cuff be inflated to 60 cm H_2O intracuff pressures.*

Table 5: LMA ProSeal™ Accessory Guidelines

LMA ProSeal™ Airway Size	Introducer Size	Largest OG Tube	Largest Salem Sump
1 1/2	#1-2 1/2	10 Fr	8 Fr
2	#1-2 1/2	10 Fr	8 Fr
2 1/2	#1-2 1/2	14 Fr	12 Fr
3	#3-5	16 Fr	14 Fr
4	#3-5	16 Fr	14 Fr
5	#3-5	18 Fr	16 Fr

OG=orogastric

Table 6: Maximum FOB and ETT Sizes (mm)

LMA™ Airway Size	LMA Classic™ LMA Unique™		LMA ProSeal™		LMA Flexible™		Single use LMA Flexible™	
	ETT	FOB	ETT	FOB	ETT	FOB	ETT	FOB
1	3.5	2.7	NA	NA	NA	NA	NA	NA
1 1/2	4.0	3.0	4.5 uncuffed	3.5	NA	NA	NA	NA
2	4.5	3.5	4.5 uncuffed	3.5	NA	2.7	NA	2.7
2 1/2	5.0	4.0	4.5 uncuffed	3.5	NA	3.0	NA	3.0
3	6.0 cuffed	5.0	5.0 uncuffed	4.0	NA	3.5	NA	3.5
4	6.0 cuffed	5.0	5.0 uncuffed	4.0	NA	3.5	NA	3.5
5	7.0 cuffed	5.5	6.0 cuffed	5.0	NA	4.0	NA	4.0
6	*7.0 cuffed	*5.5	NA	NA	NA	4.0	NA	NA

FOB=fiberoptic bronchoscope
ETT=endotracheal tube
** Applies to LMA Classic™ only, size 6 not available in LMA Unique™.*

Exhibit E

Indian J. Anaesth. 2005; 49 (4) : 308 - 318

COMPLICATIONS OF ENDOTRACHEAL INTUBATION AND OTHER AIRWAY MANAGEMENT PROCEDURES

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Introduction

Airway management is a fundamental aspect of anaesthetic practice and of emergency and critical care medicine. Endotracheal intubation (ETI) is a rapid, simple, safe and non surgical technique that achieves all the goals of airway management, namely, maintains airway patency, protects the lungs from aspiration and permits leak free ventilation during mechanical ventilation, and remains the gold standard procedure for airway management. There are also several alternatives to ETI, both for elective airway management as well as for emergency airway management when ETI is difficult or has failed. These devices include the laryngeal mask airway and the combitube. Both ETI and the use of the other airways are associated with complications, some of them life threatening. It is essential for anaesthesiologists to be aware of these complications, and to have an effective strategy to prevent and manage these complications when they arise. A large number of complications have been described. It is beyond the scope of this article to deal with each in detail; emphasis will be laid on the major, potentially life threatening and preventable complications.

Complications associated with ETI

Predisposing factors for complications[1]

The incidence and occurrence may depend on several factors. These include:

Patient factors

1. Complications are likely in infants, children and adult women, as they have a relatively small larynx and trachea and are more prone to airway oedema.
2. Patients who have a difficult airway are more prone to injury as well as hypoxic events.
3. Patients with a variety of congenital as well as chronic acquired disease may experience either difficult intubation or may be more prone to physical or physiological trauma during intubation.
4. Complications are more likely during emergency situations.

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Anaesthesia related factors

The anaesthesiologists:

1. The knowledge, technical skills and crisis management capabilities of the anaesthesiologists play a vital role in the occurrence and outcome of complications during airway management.
2. A hurried intubation, without adequate evaluation of the airway or preparation of the patient or the equipment is more likely to cause damage.

Equipment

1. The shape of the standard endotracheal tube (ETT) results in maximal pressure being exerted on the posterior aspect of the larynx. The degree of damage to these areas depends on the size of the tube and the duration of intubation.
2. Use of stylets and bougies predispose to trauma.
3. Additives to plastic may provoke tissue irritation.
4. Sterilization of plastic tubes with ethylene oxide may lead to production of toxic ethylene glycol if adequate time for drying has not been allowed.
5. Cuff related injuries might occur with the use of high pressure cuffs or inappropriate use of low pressure cuffs.

Complications that may be associated with ETI[2] are listed in Table 1. Flemming classifies hazards of ETI as those that require immediate recognition and management, those related to tissue erosion and healing, and those of lesser significance such as minor trauma.[1]

I. Complications requiring immediate recognition and management

Failed intubation

The difficult airway and failed intubation encompass a spectrum including difficult mask ventilation, difficult laryngoscopy, difficult intubation and failed intubation. The most dreaded situation is a cannot-ventilate-cannot-

Table - 1 : Complicaion of ETI[2]

At the time of intubation	While the ETT is in place
Failed intubation	Tension pneumothorax
Spinal cord and vertebral column injury	Pulmonary aspiration
Occlusion of central artery of the retina and blindness	Airway obstruction
Corneal abrasion	Disconnection and dislodgement
Trauma to lips, teeth, tongue and nose	Tracheal tube fire
Noxious autonomic reflexes	Unsatisfactory seal
Hypertension, tachycardia, bradycardia and arrhythmia	Leaky circuits
Raised intracranial and intraocular tension	Swallowed ETT
Laryngospasm	
Bronchospasm	
Laryngeal trauma	
Cord avulsions, fractures and dislocation of arytenoids	
Airway perforation	
Nasal, retropharyngeal, pharyngeal, uvular, laryngeal, tracheal, oesophageal and bronchial trauma	
Oesophageal intubation	
Bronchial intubation	

During extubation	After intubation
Difficult extubation	Sore throat
Cuff related problems	Laryngeal oedema
ETT sutured to trachea or bronchus	Hoarseness
Laryngeal oedema	Nerve injury
Aspiration of oral or gastric contents	Superficial laryngeal ulcers
	Laryngeal granuloma
	Glottic and subglottic granulation tissue
	Laryngeal synechiae
	Vocal cord paralysis and aspiration
	Laryngotracheal membrane
	Tracheal stenosis
	Tracheomalacia
	Tracheo-oesophageal fistula
	Tracheo-innominate fistula

intubate (CVCI) situation in an apnoeic anaesthetized patient.[3,4] This is a brain and life threatening emergency occurring in about 1in 10,000 anaesthetics. Failure to achieve oxygenation will result in death or hypoxic brain damage. Repeated attempts at intubation result in more morbidity, and the number of attempts should be restricted to three.[5] In an analysis of 1541 claims,[6] there were 522 (34%) adverse respiratory events. Death or brain damage occurred in 85% of these cases. The main problems were inadequate ventilation (38%), substandard care (90%), oesophageal intubation (18%) and failure to identify problem (48%). The approach to a difficult airway and the management of the difficult airway as well as failed intubation has been outlined in the ASA difficult airway algorithm.[3,4] It is beyond the scope of this article to discuss the algorithm in detail. Methods of emergency ventilation in a CVCI situation include use of the laryngeal mask, combitube or transtracheal jet ventilation. Cricothyrotomy (not tracheostomy) is the preferred method of surgical access to the airway in an emergency such as a CVCI problem. Complications associated with the laryngeal mask and combitube are detailed in a later section. The major problem with jet ventilation is the risk of barotrauma due to pressure of the oxygen jet.[7,8] The risk increases if the airway is obstructed. The ventilatory rate should be restricted to the minimum required to prevent life threatening hypoxia (4-6/min) and a cricothyrotomy or tracheostomy undertaken without delay. A second 20G cannula can be inserted to vent the expired gases.

Oesophageal intubation

Prompt recognition of oesophageal intubation is vital to prevent hypoxia in the apnoeic patient. It may be recognized by gurgling sounds over the epigastrium on auscultation, abdominal distension and absence of breath sounds on the thorax. However all such clinical tests are flawed, and precious lives and brains have been lost by relying on clinical signs of oesophageal intubation. The only certain method of confirming correct placement of the ETT is to visualise its passage though the vocal cords; unfortunately this is not possible during a difficult intubation, a common situation in which oesophageal intubation occurs. End tidal CO_2 monitoring is essential to confirm tracheal placement of the ETT. Passage of a fibreoptic bronchoscope through the ETT and visualization of the tracheal rings and carina also confirms tracheal placement, but is not universally available. Hypoxemia occurring soon after ETI may be due to unrecognised oesophageal intubation. Every attempt should be made to confirm correct placement. There may sometimes be difficulty in deciding whether the tube has been correctly placed; if there is any doubt, the tube should be withdrawn and reintroduced. The old maxim "when in doubt, take it out" still holds true.

Bronchial intubation

Endobronchial intubation occurs if too long a tube is used and inserted into one of the mainstem bronchi. Endobronchial intubation is most common when the distance for the tube tip to be placed properly above the carina yet

below the vocal cords is minimal, as in small children. Standard formulae for the correct length of the ET tube to be inserted may serve as useful guidelines. The unintubated lung does not contribute to gas exchange, and the large volume of blood flowing through this lung results in a substantial right to left shunt resulting in hypoxia. In addition, the intubated lung is hyperinflated, receiving the entire tidal volume, predisposing to overdistension and barotrauma. Signs are those of arterial hypoxaemia, including cyanosis and laboured breathing. In addition, uptake of the inhalation anaesthetic agent may be impaired, resulting in an unexpectedly light plane of anaesthesia. When endobronchial intubation is discovered, the ETT should be withdrawn several centimetres and the lungs inflated to expand atelectatic areas. Fiberoptic bronchoscopy is the optimal diagnostic tool. The clinician must be extremely careful when withdrawing the tube in awkward positions or in the difficult airway. Note also that properly placed tubes may change their position during head movement or repositioning of the patient.[9]

Spinal cord and vertebral column injury

Extension of the cervical spine during laryngoscopy may cause trauma to the spinal cord resulting in quadriplegia. This is more likely in patients with cervical spine fractures or malformations, tumours or osteoporosis. In patients with suspected instability of the cervical vertebrae, the head must be maintained in a neutral position during laryngoscopy and intubation at all times; hyperextension is strictly avoided. The head may be stabilised by in-line manual stabilisation by an assistant. Alternative techniques of airway management that do not involve neck manipulation, such as fibreoptic intubation may be considered.

Noxious autonomic reflexes

Hypertension, tachycardia, arrhythmias, intracranial and intraocular hypertension

Laryngoscopy and ETI produce reflex sympathetic stimulation and are associated with raised levels of plasma catecholamines, hypertension, tachycardia, myocardial ischemia, depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension.[10] Hypoxia and hypercarbia aggravate the autonomic response. The magnitude of the pressor response is related to the duration of laryngoscopy, and may be severe during a difficult intubation with multiple, prolonged attempts at laryngoscopy and intubation. These responses may be particularly deleterious in patients with hypertension, IHD, myocardial dysfunction and raised intraocular and intracranial pressure. In patients with limited coronary or myocardial reserve, myocardial ischemia or failure may follow. The patient with limited intracranial compliance or an intracranial vascular anomaly may suffer serious intracranial hypertension or haemorrhage.

These responses, which also occur during tracheal extubation and suction, can be minimized by rapid, smooth ETI with adequate topical anaesthesia, analgesia, sedation and perhaps the use of muscle relaxants to prevent coughing and bucking during the procedure.

Drugs that tend to block the response to airway instrumentation may be used to blunt these noxious reflex responses. These include fentanyl 3 to 4 $mgkg^{-1}$, alfentanil, lignocaine 1.5 $mgkg^{-1}$ i.v, a small dose of beta antagonist, sublingual nifedipine or intravenous nitroglycerine

Bronchospasm

The presence of an ETT in the trachea produces reflex bronchoconstriction.[11] Bronchospasm may be especially severe in the lightly anaesthetized patient with reactive airways. Bronchospasm may be blunted by the prior administration of anticholinergics, steroids, inhaled b_2-agonists, lignocaine (topical, nerve block, intravenous), and narcotics. After intubation, deepening anaesthesia with intravenous or inhaled agents and the administration of inhaled or intravenous b-agonists are helpful. It is important to ensure that the audible wheezing is not due to mechanical obstruction of the tube or other causes, such as tension pneumothorax, or heart failure.

Drying of mucosa and effects on mucociliary function

The ETT bypasses the humidifying mechanisms in the nose and upper trachea. Inadequate humidification leads to drying of secretions, depressed ciliary motility and impaired mucous clearance. The ETT also provides a surface for pathogenic organisms from the gastrointestinal tract and oropharynx to adhere to and provides direct access for these organisms into the respiratory tract.[12]

Laryngospasm

This may result from attempted intubation of the trachea under light anaesthesia. This can result in hypoventilation, inability to ventilate the lungs and hypoxia, and must be corrected by rapidly deepening the plane of anaesthesia or by giving a muscle relaxant.

Acute traumatic complications

Injury to the lips, teeth, tongue, nose, pharynx, larynx, trachea and bronchi can occur during laryngoscopy and intubation. Traumatic complications have been extensively described in two excellent reviews.[13,14] Most traumatic complications do not result in major morbidity or mortality. However, some require immediate recognition and management. In a review of closed 4,460 claims,[15] airway injuries accounted for 6%. The most frequent sites of injury were larynx (33%), pharynx (19%), and oesophagus (18%). Tracheal and oesophageal injuries were more frequent with difficult intubation. Difficult intubation, age

older than 60 yr and female gender were associated with claims for pharyngo-oesophageal perforation.

Oesophageal, tracheal and bronchial perforation

Oesophageal perforation can occur with attempts at intubation, especially in patients with a difficult airway or multiple attempts. Subcutaneous emphysema may be noticed soon after intubation. Later, neck pain, difficulty in swallowing, neck erythema, and oedema may occur. Mediastinitis leading to sepsis may result in death or serious morbidity. Placement of a nasogastric tube has also been associated with oesophageal perforation.

Tracheal laceration may occur due to overinflation of the ETT cuff, multiple intubation attempts, use of stylets, malpositioning of the tube tip, tube repositioning without cuff deflation, inadequate tube size, vigorous coughing, and nitrous oxide in the cuff. The risk is also greater in patients with tracheal distortion caused by neoplasm or large lymph nodes, weakness in the membranous trachea (seen in women or the elderly), chronic obstructive lung disease, and corticosteroid therapy.

Endobronchial injury can occur with instrumentation of the bronchi. Endotracheal tube guides or tube changers have been associated with endobronchial rupture.[16] Placement of double-lumen ETTs has also been associated with tracheobronchial rupture.[17]

Airway perforation may occur anywhere from the nose to the trachea. It may admit air into unusual locations and manifest as subcutaneous emphysema, pneumomediastinum and pneumothorax. When these occur, a search must be made for such perforations, including by bronchoscopy. Nitrous oxide should be discontinued when pneumothorax or pneumomediastinum is suspected. In awake patients, cough, hemoptysis and cyanosis may occur.

Tension pneumothorax

This can lead to severe hypoxia and hypotension, and can occur after airway perforation during intubation or due to barotrauma during IPPV. It must be suspected either when there is unexplained hypoxia and hypotension, or when they occur with any of the signs of airway perforation. Airway pressure is increased, ventilation of the lungs may be difficult, breath sounds are absent on the affected side with a mediastinal shift to the opposite side, there is a hyper resonant note on percussion, and breath sounds are diminished or absent. An urgent X-ray chest confirms the diagnosis, but in the presence of cardiorespiratory compromise, the pneumothorax must be urgently decompressed by inserting a wide bore cannula in the 2nd interspace on the affected side.

Disconnection and dislodgement

Accidental dislodgment of the ETT during anaesthesia is a potentially lethal complication. Extension of the neck may cause cephalad movement of the ETT tube. Poor or loose fixation of the tube, excessive movement of the head during surgery, inadequate access to the tube during head and neck surgery or neurosurgery and heavy connectors producing drag on the circuit and ETT may lead to dislodgement. It can be detected rapidly if airway pressure and capnography are being continuously monitored. In the intensive care unit, the longer a tube stays in-situ, the greater the chances of kinking, blockade and unplanned extubation, leading to hypoventilation and hypoxia. Unplanned extubations have reported an incidence ranging from 0.3–30 %.[18,19] Inadequate sedation, agitation, inadequate nursing supervision and inadequate fixation of the ETT predispose to accidental extubations in the ICU.[20]

Failure to achieve satisfactory seal

Inadequate cuff seal is a common problem, leading to hypoventilation during Mechanical Ventilation (MV) and aspiration of gastric contents. The common causes of leak during MV and their solutions are outlined in Table-2. More serious causes[21] include tracheomalacia and tracheo-oesophageal fistula [TEF]. Inflation of the cuff leads to weakening of tracheal cartilage and widening of the trachea. Progressively increasing volumes of air are then required to maintain cuff seal.

Table - 2 : Common problems leading to leak during mechanical ventilation.[21]

Problem	Solution
Eccentric cuff inflation	Check cuff before insertion
Incorrect cuff position, cuff at or above vocal cords	Check and adjust ETT position, ensure cuff is in mid-trachea
Size of ETT is too small	Change ETT, insert a larger ETT
Leak in inflation valve	Attach 3-way stopcock and keep closed to maintain seal
Leak in pilot balloon or valve	Cut the connecting tube distal to leaking part housing and insert 22G needle with 3-way stopcock into remaining tubing
Leaking cuff, usually damaged by teeth, nasal bone or Magill forceps	Change ETT

Obstruction of the tube[2,9]

This can be due to a number of reasons :

1. Biting of the ETT.
2. Kinking of the ETT.
3. Obstruction by material in the lumen of the tube. This includes inspissated secretions, blood clots, nasal turbinates, adenoids or a variety of foreign bodies.

4. Defective spiral embedded tubes. During manufacture, air bubbles may form between layers. Blebs form when these are steam sterilized with vacuum. Diffusion of nitrous oxide into these blebs causes dissection of the walls with compression of the lumen.
5. Impaction of the tip of the tube against the tracheal wall may result in respiratory obstruction, particularly where the trachea contains a sharp bend, such as the thoracic inlet. The Murphy's eye, incorporated into many modern tubes, permits airflow to take place, even if this has occurred.
6. Herniation of the cuff over the lumen of the tube may occur if the cuff of an old, perished tube is over inflated. This, again, will cause respiratory obstruction.
7. Compression of the lumen of the tube by the cuff may be caused by over inflation of the cuff or by gradual diffusion of nitrous oxide onto the cuff during the course of anaesthesia. This problem is more common when silicone rubber tubes are used.

Obstruction of the ETT may manifest as increased resistance to ventilation, high airway pressures and 'wheeze'. A blocked tube is an important cause of intraoperative bronchospasm and must be ruled out before bronchodilator therapy is given. ETT obstruction may be prevented by careful attention to the type of ETT, inspection and checking of the ETT and cuff prior to use, and by humidification of inspired gases. When ETT obstruction is diagnosed, visual inspection, passage of a suction catheter (or preferably a fiberoptic bronchoscope) along with cuff deflation and 90^0 rotation of the tube will rule out several of these possibilities. If patency cannot be restored, the ETT should be removed and replaced, if necessary over a tube exchanger.

Aspiration of gastric contents

While a cuffed tube protects the lungs from aspiration of foreign material, aspiration does occur. The high volume low pressure cuff has folds even after inflation through which fluid can pass into the trachea and lungs. The presence of spontaneous ventilation, accumulation of fluid above the cuff, a head up position and the use of uncuffed tubes or cuff leakage increase the chances of aspiration.

Fire during laser surgery[9]

Fires are a danger associated with the increasing use of lasers for airway and oral surgery. Steps that may be taken to reduce this extremely serious hazard include:

1. Using special laser tubes, which may be made of jointed metal or clear plastic (with no radiopaque strip), or a plain red rubber tube, but not a conventional plastic tube.
2. Wrapping exposed portions of the tube with aluminium tape.
3. Inflating the cuff of the ETT with saline instead of air.
4. Packing wet pledgets between the ETT and larynx and covering the external part of the ETT with wet drapes.
5. Use of helium-oxygen mixtures that are less supportive of combustion than oxygen alone or oxygen-nitrous oxide mixtures.

When a fire in the airway occurs, the flow of oxygen must be immediately stopped, saline poured on the ETT and the trachea extubated. Surgery is stopped, the trachea is reintubated and the patient given humidified oxygen. The airway should be examined for burn injury and for any missing fragments of the ETT or its wrapping.

Difficult extubation[10]

1. The cuff may fail to deflate. It can be punctured by a needle placed through the cricothyroid membrane after the cuff is raised to this level.
2. More serious and somewhat unusual causes of difficult extubation include fixation of the ETT or pilot tube by a Kirshner (K) wire used in head and neck surgery or a suture placed from the pulmonary artery through the trachea into the ETT. The nature of the surgical procedure must be kept in mind when a tube will not come out after cuff deflation or rupture, so as to avoid trauma from vigorous extubation attempts. Direct or fiberoptic examination may be required.

Complications of extubation[10]

Airway obstruction, laryngospasm, and aspiration can occur. After intubations lasting 8 hours or more, airway protection may be impaired for 4 to 8 hours.

Sore throat is a complication of anaesthesia that may have pharyngeal, laryngeal, and/or tracheal sources and may occur in the absence of ETI. Factors that may affect the incidence of sore throat include area of cuff trachea contact, use of lignocaine ointment and size of the ETT, and the use of succinylcholine. Cuffs with a longer cuff trachea interface appear to cause a higher incidence of sore throat. The incidence of sore throat may also be related to intracuff pressures. The mechanism for succinylcholine-related sore throat is postulated to be myalgias due to fasciculations of peripharyngeal muscles. Sore throat is a minor side effect that should resolve within 72 hours; it should not be a factor in determining whether ETI is required.

Hoarseness is another minor side effect correlated with ETT size that should be investigated if persistent.

Laryngeal oedema[10]

Subglottic oedema is particularly more common in children, as the nonexpandable cricoid cartilage is the narrowest part of the pediatric airway. Oedema may also be uvular, supraglottic, retroarytenoid, or at the level of the vocal cords, and is manifested by inspiratory stridor. Diminished stridor may represent total airway obstruction and movement of air must be repeatedly confirmed. The contributing factors to the production of laryngeal oedema include too large a tube, trauma from laryngoscopy and/or intubation, excessive neck manipulation during intubation and surgery, excessive coughing or bucking on the tube, and present or recent upper respiratory infection. The prophylactic use of steroids before extubation to reduce oedema is an unproven but frequently utilized treatment if the likelihood of postextubation stridor is suspected. Treatment includes warmed, humidified oxygen, nebulized racemic epinephrine (0.25 to 1 ml), and I.V. dexamethasone (0.5 $mgkg^{-1}$ up to 10 mg). If obstruction is severe and persistent, reintubation must be considered.

Acute traumatic complications of lesser significance[13,14]

Dental injury

Incidence of dental injury ranges from 1:150 to 1:1000, to as little as 1:9000.[22] The upper incisors are usually involved. Risk factors include preexisting poor dentition and one or more indicators of difficult laryngoscopy and intubation.[23] When dental trauma occurs, the loose tooth should be recovered to ensure that aspiration of the tooth does not occur. The avulsed tooth should be placed in saline and immediate dental consultation should be obtained for possible reimplantation. A partial or complete dental fracture should be evaluated by an oral surgeon postoperatively. Details of the injury should be well documented in the anaesthetic record and chart and the patient informed of the injury.

Nasal injury

Nasotracheal intubation is frequently used in head and neck surgery. Patients with basilar skull fractures or severe facial trauma should not have nasal tubes passed as there exists a danger of inadvertent cranial intubation.

Epistaxis is a common problem, caused by the tip of the ETT traumatizing nasal and pharyngeal mucosa. This may be more common and dangerous in patients with coagulopathy or those receiving anticoagulants. Nasal intubation is relatively contraindicated in such patients.

Attempted passage of a nasotracheal tube can create false submucosal passages. These can progress to retropharyngeal abscesses.

Turbinates, adenoids, and tonsils can also be traumatized. Prolonged nasal intubation can lead to pressure necrosis of the nostrils and septum. Nasal septal abscesses, retropharyngeal abscesses and paranasal sinusitis can occur after intubation. Paranasal sinusitis[24] occurs due to injury to the sinus ostia followed by oedema, obstruction and infection. It may present as unexplained fever or purulent discharge, is often refractory to antibiotics and may lead to intracranial infection or septicaemia.[25]

Pharyngeal trauma

Necrosis and perforation of the pharynx may present in the immediate postoperative period with subcutaneous crepitus, fever, tachycardia, and odynophagia. Most lacerations of the oropharynx can be treated conservatively. A haematoma should be treated with antibiotics, but if it is large, consideration should be given to drainage. The patient must avoid oral feeds for at least 48 hours and intravenous broad-spectrum antibiotics should be prescribed. Larger perforations may need surgical repair.

Temporomandibular joint injury

Patients tend to be healthy females below 60 years of age. Preexisting temporomandibular disease may be present in a small percentage. The dislocation usually is detected at the time of procedure and the jaw is locked in an open position and cannot be closed. Immediate reduction of the dislocated TMJ should be performed and this can be achieved easily. Patients with continual symptoms referable to the joint should receive an oral surgery consultation for possible treatment with an occlusal appliance.

Tongue injury

Macroglossia occurs due to prolonged compression by an ETT or oral airway, leading to ischemia and venous congestion. Obstruction of the submandibular duct by an ETT may lead to massive tongue swelling.[26] Compression injury to the lingual nerve during difficult intubation leading to loss of sensation has been reported.

Laryngeal trauma

Vocal cord paralysis

In the subglottic larynx, an anterior branch of the recurrent laryngeal nerve enters between the cricoid and the thyroid cartilage, innervating the intrinsic muscles of the larynx. An inflated cuff at this location can compress the nerve between the cuff and the overlying thyroid cartilage, causing injury.[27,28] Bilateral injuries present considerably more risk and frequently require emergency reintubation or tracheostomy. Unilateral injury to a

recurrent laryngeal nerve prevents abduction of the ipsilateral vocal cord; therefore, it becomes fixed in the adducted position. This is associated with hoarseness, usually noted immediately in the postoperative period. Recurrent nerve injury can be prevented by avoidance of overinflation of the ETT cuff, and prevention of excessive tube migration during anaesthesia. Vocal cord paralysis is usually associated with spontaneous recovery over days to months.

Arytenoid injury

Arytenoid dislocation is another well described cause of laryngeal injury that can occur after traumatic intubation[29] as well as with routine elective intubation.[30]

II. Complications related to tissue erosion and healing

Laryngeal injury : Occurs due to ischemic injury resulting from high pressures generated [upto 400 mmHg] when the round ETT presses on the pentagonal structure of the larynx, especially at the vocal processes of the arytenoids and the cricoid ring.[31]

Ulcerations or erosions of the larynx : Are common even after a short duration of intubation, and progress with the length of intubation. They are most commonly found on the posterior part of the larynx and anterior and lateral aspects of trachea, corresponding to the position of the convex curve of the ETT, the tip and the cuff. Superficial ulcers heal rapidly. Deeper ulcers may result in scarring or erosion of a blood vessel and haemorrhage.

Granuloma of the vocal cords : May develop from an ulcer, when granulation tissue forms and forms a sessile lesion. The incidence varies from 1: 800 to 1: 20000. Patients may be asymptomatic, or have hoarseness, pain and discomfort in the throat, chronic cough and haemoptysis. Persistent symptoms after intubation need an ENT consult and strict voice rest. Granulomas usually heal spontaneously. Surgical intervention is required only if the lesion is pedunculated or the patients develops respiratory obstruction.

Laryngotracheal membrane : Is an uncommon but potentially fatal complication due to respiratory obstruction. The symptoms of respiratory obstruction occur 24-72 hours after extubation. Diagnosis is made by direct laryngoscopy or bronchoscopy. Treatment is removal by suction.

Delayed tracheal injury : Is almost always cuff related, and can be minimized by use of low pressure cuffs and meticulous cuff management. The incidence of laryngotracheal complications can be further reduced by use of appropriate sized ETTs made of nontoxic plastic. Drag on the ETT by ventilator tubing should be avoided and excessive ETT movement reduced by use of swivel connectors. Local and systemic sepsis should be aggressively treated and corticosteroids used only when indicated.

Tracheal stenosis : Intracuff pressure is transmitted laterally against the wall of the trachea. Ischemia and eventual necrosis occur when the lateral tracheal wall pressure exceeds the capillary perfusion pressure of about 25 mmHg. Necrosis of the tracheal mucosa leads to sloughing and ulceration of the mucosal membrane, exposing tracheal cartilage. Continued ischemia may be followed by partial or complete destruction of cartilaginous tracheal rings and loss of the structural integrity of the affected tracheal segment, leading to tracheal dilatation. Healing of the injured tracheal segment during any stage of this process may lead to a tight fibrous stricture (tracheal stenosis). These can be prevented by proper management of low pressure cuffs. Only high volume, low pressure cuffs must be used, and the cuff inflated to pressure not exceeding 25 mmHg or 30 cm H_2O. Overinflation of these cuffs causes them to function just like high pressure cuffs. It is therefore essential to inflate only as much air as is required to just seal the air leak during IPPV (minimal inflation technique), and to check the intracuff pressure with a cuff-pressure manometer.

Complications of tracheostomy

Two types of tracheostomy (TR) are now performed – open or surgical tracheostomy, and percutaneous tracheostomy. The complications of TR[32-34] are summarized in Table 3. Some of these are:

Table - 3 : Complications of tracheostomy

A.	**Complications during surgery**
	Haemorrhage
	Pneumothorax and pneumomediastinum
	Cardiorespiratory arrest
	Recurrent laryngeal nerve injury
B.	**Immediate postoperative complications**
	Haemorrhage
	Subcutaneous emphysema
	Displacement and obstruction of the tube
	Swallowing problems
C.	**Late complications**
	Tracheal stenosis: at the stoma or at the level of the cuff
	Tracheomalacia
	Tracheo-oesophageal fistula
	Tracheo-innominate fistula

1. **Pneumothorax :** Occurs in about 4% of adult TRs and is more common during emergency or difficult TR, especially when the airway is obstructed and the patient's inspiratory efforts draw in a large volume of air into tissue planes. False passage of the tracheostomy tube (TT) in the anterior paratracheal tissue followed by mechanical ventilation (MV) leads to similar complications. Tension pneumothorax may lead to cardiac arrest. A chest X ray must be taken after TR and if pneumothorax is present, it should be promptly treated by drainage and underwater seal. Subcutaneous emphysema can be prevented by using a cuffed TT and by not suturing the wound very tightly.
2. **Cardiorespiratory arrest :** The respiratory drive and massive sympathetic stimulation occurring due to hypercarbia and hypoxia in patients with severe airway obstruction are suddenly removed when TR is performed, leading to respiratory arrest and cardiovascular collapse. The patient usually recovers completely with MV, fluid resuscitation and inotropic support. Negative pressure pulmonary oedema[36] may also occur minutes to hours after airway obstruction is relieved by TR [or ETI]. It responds well to treatment.
3. **Inability to insert the TT** : Can result in severe hypoxia and death. During TR, the ETT should never be withdrawn completely from the larynx until it is confirmed that the TT is in the trachea. The TR tract takes 37 days to form. If in this period, the TT needs to be reinserted, there is a real danger of being unable to reinsert the tube or of inserting it into the paratracheal space. A pad must be placed under the shoulders to bring the trachea up in the neck and a tracheal dilator used to introduce the TT. ETI may be necessary to secure the airway if the TT cannot be replaced. A Bjork flap [an inverted 'U' shaped flap of anterior tracheal wall cut and sutured to the skin] may permit easier reinsertion of the TT before the tract has formed, but may be associated with a higher incidence of stomal stenosis.
4. **Trachea stenosis and tracheomalacia** : Can be prevented by proper management of low pressure cuffs. The incidence of stomal stenosis can be reduced by not making a large stoma and by use of lightweight, mobile, swivel connectors to minimize mechanical trauma.
5. **Tracheo-oesophageal fistula** : May occur due to injury to the posterior tracheal wall during TR, but is more often the result of high cuff pressures, and is often aided by a nasogastric tube pinched between the oesophagus and posterior tracheal wall.
6. **Tracheo-innominate fistula**[37] : Is a dreaded complication of TR, the patient exsanguinating to death in minutes. It is a major cause of haemorrhage occurring 48 hours after TR and occurs either due to direct contact between the innominate artery and TT in case of low TR [below the 4 th tracheal ring] or to high cuff pressures leading to necrosis of the anterior tracheal wall followed by erosion of the arterial wall. Major haemorrhage may be preceded by 'warning bleeds' and the TT may be seen to be pulsating. Haemorrhage may be controlled by hyperinflating the cuff to occlude the opening in the artery. If this is unsuccessful, the artery can be compressed anteriorly after incising the skin over the sternal notch while the patient is transported to the operating room. Immediate surgery is required to salvage the patient.

Complications of percutaneous tracheostomy

The incidence of complications reported with PCT varies from 3-25%, In three large series using the Ciaglia technique, perioperative complications were reported in 8-11% of patients.[38-40] The published incidence of perioperative complications with the guidewire dilating forceps (GWDF) technique[41-43] ranges from 0-24%. Fikkers and Ambesh found no major differences between the GWDF and the Blue Rhino techniques,[44,45] except perhaps for a slightly increased bleeding with the GWDF.[45] In a meta analysis of percutaneous tracheostomy trials (n=27; patients) 1817 perioperative complications occurred in 10%, including deaths in 0.44% and serious cardiorespiratory events in 0.44% patients, whereas postoperative complications occurred in 7% of patients.[46] The main perioperative complications of PCT include bleeding, pneumothorax, and posterior tracheal injury. Posterior tracheal injury may be confined to the mucosa, or may involve the entire posterior wall, and more seriously, result in a tracheo-oesophageal fistula. It has been suggested that visualization by fibreoptic bronchoscopy of tracheal puncture and dilatation can substantially reduce the incidence of such complications.[47,48] Endoscopic guidance ensures midline placement, prevents paratracheal tube placement and avoids inadvertent injuries. Complications during percutaneous tracheostomy have been classified[46] as major, intermediate and minor (table 4).

Table - 4 : Complications of percutaneous tracheostomy

Major	Intermediate	Minor
Death or cardiac arrest Pneumothorax Post tracheal tear Tracheo-oesophageal fistula Intratracheal haemorrhage Pulmonary aspiration of blood Obstruction or displacement of the tube Sepsis Tracheal stenosis	Hypoxemia Bleeding (requiring surgical intervention, blood transfusion or hemoglobin fall > 2gm%) Posterior tracheal wall injury Conversion to surgical tracheostomy Abandoned procedure	Minor Haemorrhage Subcutaneous emphysema Pretracheal dilatation Puncture of ETT cuff Arterial puncture

Complications with the laryngeal mask airway

The laryngeal mask airway (LMA) has become an increasingly popular alternative to the face mask and ETT as a means of providing a secure airway for patients undergoing elective surgical procedures requiring general anaesthesia. However, the use of LMA is not free of complications. These have been reviewed by Pollack.[49] Complications resulting from use of the LMA in the OR are known to be rare. In a series of more than 11,000 patients of all ages over a 2-year period, there was a 0.15% airway management complication rate, and none of these 18 patients required intensive care.[50]

Malplacement and aspiration

The commonest and the most important are regurgitation of gastric content and chances of aspiration. Brimacombe conducted a meta analysis of the published literature and found an incidence of aspiration in 2/10,000 patients, which is similar to that recorded during general endotracheal anesthesia.[51] The LMA has been shown to cover both the laryngeal inlet and the oesophagus, thus forming a potential direct communication between the two. Moreover LMA does not reliably provide an airtight seal around the larynx and may not protect the airway from aspiration of gastric contents, if there is regurgitation into pharynx. The chance of regurgitation and aspiration while using LMA is present both during spontaneous and mechanical ventilation. The incidence of regurgitation varies from 0.08 to 23%.[52-53] Mechanical ventilation with an LMA may encourage the risk of reflux and aspiration more, by causing gastric insufflations and increased intragastric pressure.[54] Regurgitation is considered to occur more often during certain surgical procedures, such as laparoscopic surgery in gynaecological patients. This is thought to be due to lithotomy position with head down tilt which increases intra abdominal pressure,[55] there is also the possibility that the LMA induces a reduction of lower oesophageal sphincter tone.[56] Malplacement and improper seating of the LMA above the airway opening clearly increases the risk of gastric distension and subsequent aspiration, as does positive pressure ventilation through the LMA. There are case reports of aspiration even with Proseal LMA.[57]

Inadequate patient anaesthesia may result in coughing, gagging, and bucking on attempted LMA insertion. This may be particularly hazardous in the patient with suspected intracranial or cervical spine injury. If coughing and gagging occur during attempted insertion, the mask should be removed and anaesthesia should be deepened. If they occur with the mask in situ, anaesthesia should be deepened and the mask should be left in place. Direct trauma to pharyngeal and upper airway structures typically may result from poor insertion technique.

Malplacement of the LMA, with migration of the LMA tip into the glottic aperture, may also induce bronchospasm. Ventilation through an LMA in these patients may be inadequate because high positive pressure ventilation results in air leak around the laryngeal mask.

Pressure induced lesions

The next important complication, which has been reported, is lingual nerve injury, both unilateral and bilateral. The course of lingual nerve after it branches out of posterior trunk of mandibular nerve is such that the various manoeuvers undertaken during the insertion of LMA and in maintaining its position can injure it. The nerve is vulnerable to compression as it travels between the pterygoids or between the medial pterygoid and the mandible. Compression injury between the pterygoids may occur secondary to mandibular retraction.[58] Prolonged anterior displacement of the mandible, as in the jaw thrust manoeuver, has also been implicated in lingual neuropraxia. The LMA can also cause nerve injury probably by direct compressions of the nerves. When the laryngeal mask is correctly placed, the distal tip lies in the hypopharynx at the upper oesophageal sphincter, the proximal base lies just under the tongue base with sides facing the pyriform fossa.[59] In this position the cuff may compress the lingual nerves as they lie on the inner aspect of the mandible covered only by the mucus membrane.[60]

Tongue cyanosis and swelling has also been reported after the use LMA.[61] The probable cause may be occlusion of lingual artery bilaterally by the cuff of LMA when the arteries enter the base of tongue. It may be due to malpositioning or due to size of LMA.

The incidence of recurrent nerve paralysis has also occurred by the use of LMA. The probable cause may be the compression of the nerve by increased cuff pressure of the LMA at the point where the nerve enters into the larynx passing behind the thyroid and cricoid cartilage.

Cuff volume also influences postoperative sore throat and dysphagia. The incidence of sore throat has

also been found to be higher in case of LMA than that of ETT. It has been found that sore throat incidence is less with Soft-Seal LMA than classic LMA.[62] Nitrous oxide tends to diffuse less into the Soft Seal cuff during anaesthesia.

Complications of using the esophageal tracheal combitube (ETC)

The combitube has been widely accepted as an airway device for out-of hospital Cardio pulmonary and cerebral recuritation (CPCR) but has not been accepted into routine anaesthesia practice. The main limitation of the ETC in routine anaesthesia is the potential risk of trauma.

Oesophageal and pharyngeal perforation leading to subcutaneous emphysema, pneumomediastinum and pneumoperitoneum has been reported in association with out of hospital airway rescue.[63,64] Bleeding (36-45%), sore throat (16-46%) and dysphagia (8-68%) have been reported in association with routine anaesthesia.[65,66] Possible mechanisms for trauma are direct injury during placement or high pressures exerted against the surrounding mucosa.

The chances of direct injury during the placement of ETC are due to the following reasons:

1. ETC is a large and stiff tube with an anterior curvature, a design that might cause injuries by bulging the anterior wall of oesophagus. Laceration has been observed on the anterior wall only.
2. Technique of blind insertion with out visualization of the passage of the ETC into the pharynx and into the proximal oesophagus opening may also promote injuries.

The volume of both the proximal and the distal cuffs determines the pharyngeal, oesophageal and tracheal mucosal pressures. Pharyngeal mucosal perfusion is progressively reduced when mucosal pressure increases from 34 to 80 cmH_2O.[67] In the pharynx and in the oesophagus the pressure will be highest posteriorly because the posterior surface is adjacent to the rigid vertebral bodies.[68] In the pharynx the ETC can potentially impair the perfusion in the anterior, lateral and posterior wall when the proximal cuff volume increases from 40 to 70 ml, 50 to 80ml, and 30 to 50 ml respectively.[68] These volume frequently exceed the minimal volume required to form an oropharyngeal leak pressure of 30 cm H_2O.

In the oesophagus perfusion would be potentially impaired in the anterior, lateral and posterior oesophagus when distal cuff volume increases from 12 to 18 ml, 12 to 20 ml and 4 to 8 ml respectively. Likewise tracheal mucosal perfusion is progressively reduced when mucosal pressure increases from 30 to 50 cmH_2O. Tracheal perfusion would be potentially impaired in the anterior, lateral and posterior trachea, when distal cuff volume increases from 4 to 6 ml, 8 to 10 ml and 10 to 12 ml, respectively. Thus at the recommended inflation volume for the pharyngeal (85 ml) and oesophageal cuffs (10-15 ml), mucosal pressure would be potentially higher than perfusion pressure posteriorly.[68]

In the pharynx, the increased pressure may cause bleeding and sore throat and would perhaps predispose to pharyngeal perforation. Likewise, in the oesophagus these high pressures may cause dysphagia and may predispose to oesophageal rupture.

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